IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION **This Order Relates to: All Actions**	MDL No. 2641 **CASE MANAGEMENT ORDER NO. 2**

The Court held a lengthy case management conference with the parties on October 29, 2015. Before the conference, the parties submitted a proposed agenda and a memorandum setting forth positions of Plaintiffs and Defendants on various issues. Doc. 174. The Court entered an order with a more detailed agenda on October 19, 2015. Doc. 203. This order will generally follow the topics set forth in the Court's agenda.

I. Identification and Selection of Parties' Leadership.

The Court has entered Case Management No. 1, which establishes Plaintiffs' Leadership Counsel. By **November 6, 2015**, Plaintiffs' Lead/Liaison Counsel shall submit to the Court a proposed Case Management Order concerning: (a) the duties and authority of Plaintiffs' Leadership Counsel in coordinating pretrial practice in this MDL; (b) the establishment and operation of a common fund for eventual payment and reimbursement of attorneys and their firms for common benefit work; (c) a procedure for auditing the common benefit work of Plaintiffs' attorneys and their firms; (d) a procedure for making quarterly reports to the Court regarding the audits and the common benefit work performed by attorneys and their firms; (e) guidelines for eventual fee applications and cost reimbursement, including record-keeping requirements, time-keeping

requirements (*see*, *e.g.*, Local Rule of Civil Procedure 54.2(e)), staffing limitations for various tasks, acceptable hourly rates, when travel time can be billed, reimbursable expenses (what is and is not reimbursable), and acceptable levels of expense reimbursement; (f) procedures or agreements designed to avoid the duplication of common benefit discovery already completed in some of the MDL cases; and (g) periodic status reports on coordination with state cases and other relevant matters.

II. Protective and Rule 502 Orders.

By **November 6, 2015**, the parties shall jointly submit to the Court a proposed protective order, including Rule 502 provisions, for all cases in this MDL. If the order addresses the filing of confidential documents in court, it shall not say that such documents may be filed under seal. Instead, it should say that any party seeking to file a confidential document under seal shall comply with Local Rule of Civil Procedure 5.6.

III. ESI Protocol.

By **November 30, 2015**, the parties shall jointly present to the Court an ESI Protocol addressing format of production, preservation, and other relevant ESI-discovery matters. If the parties are unable to reach agreement on all aspects of the ESI Protocol, they shall file a joint report setting forth the areas of agreement and disagreement and recommending a procedure for resolving disagreements.

IV. Discovery.

A. Discovery Relevant Only to Individual Cases.

By **November 6, 2015**, the parties shall propose to the Court profile forms to be completed by Plaintiffs and Defendants with respect to each new case added to this MDL. The intent will be to provide the parties with basic and relevant information about each new case. With the exception of bellwether cases, the Court generally will not oversee discovery relevant only to individual cases. It is anticipated that such discovery will be conducted in transferor districts after this MDL is completed.

/ / /

/ / /

B. Binding Effect of Completed Discovery.

The parties will discuss whether agreement can be reached on the binding effect already-completed discovery will have in cases filed after the date of the discovery. If the parties are able to reach agreement, they shall jointly submit a stipulation to the Court by **December 18, 2015**. If the parties are unable to reach agreement, each side shall file a 10-page memorandum setting forth its position with respect to the effect of the already-completed discovery by **December 18, 2015**. Each side may file a 5-page response memorandum by **January 8, 2016**.

C. First-Phase Discovery.

By **January 15, 2016**, the parties shall complete a first phase of MDL discovery which includes the following:

1. Defendants shall provide an updated production of complaint (adverse event) files relating to the Recovery, G2, G2X, and G2 Express filters, and shall produce complaint (adverse event) files relating to the Eclipse, Meridian, and Denali filters.

2. Defendants shall produce updated versions of Bard's Adverse Event Tracking System for the various filters set forth immediately above.

3. By **November 10, 2015**, Defendants shall produce the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter.

4. Plaintiffs may take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter.

5. Kay Fuller shall be deposed.

D. Conferences Regarding Second Phase of Discovery.

The parties shall meet and confer with respect to the following discovery issues, and, by **January 20, 2016**, provide the Court with a joint report regarding their discussions. Areas of agreement and disagreement will be clearly identified, and each

party's position shall be set forth. The parties shall propose, jointly if possible, procedures for resolving their disagreements.

1. Updated collections and productions of previously searched "custodians" and ESI sources. In discussing this topic, the parties should avoid duplicative discovery, but relevant information not previously searched for should be considered as a possible subject of discovery.

2. Production of ESI from custodians involved with later-generation filter devices or employed at later time frames.

3. Further discovery related to the FDA inspection and warning letter.

4. ESI and documents that have been previously withheld, if any, as to Defendant's later-generation devices, such as the Eclipse, Meridian, and Denali filters.

5. Discovery related to the Simon Nitinol filter.

6. Discovery regarding the Recovery Cone Removal System design, design changes, corrective actions, reasons why design changes were made, regulatory communications, and adverse event reports.

7. Custodial files and other discovery with respect to sales and marketing personnel. In addressing this issue, the parties should consider whether discovery focusing on higher-level sales and marketing personnel should be undertaken before discovery of lower-level personnel. The parties should also consider whether sales and marketing discovery should be postponed until case-specific discovery is undertaken with respect to bellwether cases.

8. Pending Rule 30(b)(6) deposition notices in cases consolidated in this MDL or state-court cases.

9. Additional depositions of corporate and third party witnesses.

10. Rule 26 expert disclosures and expert depositions.

11. Discovery related to ESI preservation issues.

/ / /

/ / /

V. Issues to be Briefed.

A. Lehmann Report.

Defendants shall file a motion for protective order with respect to the Lehmann Report, including evidentiary material, by **November 30, 2015**. Plaintiffs shall file a response, including evidentiary material, by **December 18, 2015**. Defendants shall file a reply by **January 8, 2016**. The parties' briefs should address whether the Lehmann Report constitutes work product, whether an evidentiary hearing is needed, and what effect the Court's ruling should have in cases where this issue has already been decided.

B. Privilege Logs.

By **November 13, 2015**, Defendants shall provide to Plaintiffs the current version of all privilege logs. By the same date, Defendants shall identify for Plaintiffs all documents that previously were listed on privilege logs but subsequently were produced to Plaintiffs. A chart showing privilege log control numbers and bates numbers of produced documents likely would be most helpful.

Between November 13, 2015 and early January, 2016, the parties should engage in the informal privilege log exchange proposed by Defendants during the case management conference. The purpose of this exchange will be to see if the parties can reach agreement on privilege log issues. For purposes of the informal exchange, the parties should apply the work product law set forth in the magistrate judge's decision in the Nevada case, unless they agree upon different legal standards. This paragraph will not preclude parties from arguing for a different legal standard if privilege log issues must be resolved by the Court.

By **January 20, 2016**, the parties shall provide the Court with a joint report on their privilege log efforts, identifying areas of agreement and disagreement, setting forth the parties' positions on the disagreements, and proposing procedures for resolution of any remaining outstanding issues.

/ / /

/ / /

VI. Pleading and Filing Procedures.

By **November 30, 2015** the parties shall provide to the Court a master complaint drafted by Plaintiffs, a master answer drafted by Defendants, and templates of short-form complaints and answers agreed upon by the parties. The parties shall also submit to the Court a proposed case management order which provides that the master complaint and master answer will be filed in the master docket in this MDL proceeding; that new cases may be filed in the District of Arizona using the short-form complaint; that filing of a short-form complaint in the District of Arizona will not mean that the trial in that case will be held in Arizona, but instead will mean that the case will be transferred to the appropriate home district at the conclusion of this MDL; that Defendants may file a short-form answer in response to a short-form complaint; and that service of process in cases filed in the District of Arizona using the short-form complaint may be made by email on defense counsel.[1]

The parties shall include in the jointly-submitted case management order a provision identifying cases in which the master complaint and master answer will not become the operative pleadings – where the existing complaints and answers will remain the operative pleadings. The master complaint and answer will become the operative pleadings in all other cases in this MDL.

VII. Handling of Advanced Cases.

This MDL includes some cases in which discovery and motion practice has been completed. The Court does not intend to reopen already-decided *Daubert* motions or motions for summary judgment in these cases. The parties agree, however, that these cases should not be remanded to transferor courts at the present time. Rather, they will remain a part of the MDL and will be considered as possible bellwether cases in the future.

---

[1] The parties should address an additional issue in their November 30 filing. If cases are filed in Arizona under such a case management order, what is the legal basis upon which they later would be transferred to their home district? Because they would not originally have been filed in another district, transfer under 28 U.S.C. § 1407(a) presumably would not be available.

VIII. Coordination with State Court Litigation.

Plaintiffs' Lead/Liaison Counsel shall, through the Plaintiffs' Steering Committee, coordinate discovery and motion practice in this MDL proceeding with state court cases. As an immediate matter, Plaintiffs' counsel shall coordinate discovery of Hill & Knowlton with state cases.

IX. Next Case Management Conference.

The Court will hold a second case management conference on **January 29, 2016 at 9:00 a.m.** The parties should file a joint report and proposed agenda by **January 20, 2016**, identifying issues to be addressed at the conference.[2] The purpose of the conference will be to address matters raised in the joint report and the various filings identified above. The Court will establish a second phase of fact discovery on the basis of the parties' submissions and discussions at the case management conference. The Court will also confer with the parties about a schedule for expert disclosures, depositions, and *Daubert* motions. Because many of the cases in this MDL proceeding have involved no expert discovery, the Court concludes that full Rule 26 disclosures, followed by depositions and *Daubert* motions, should be conducted in this MDL. The effect of that discovery and motion practice in cases where experts have already been disclosed will be addressed later.

X. Other Matters.

A. Settlement Talks. After conferring with the parties, the Court concluded that it should not require global settlement talks at this stage of the litigation. The number and nature of cases to be added to this MDL is yet to be determined, and the scale of this litigation will be an important factor in settlement efforts. The Court will raise this issue with the parties in the future.

B. Discovery Disputes. The parties shall not file written discovery motions without leave of Court. If a discovery dispute arises, the parties promptly shall contact

[2] Among other topics, the joint report should identify pending motions in all MDL cases and set forth the parties' recommendation as to what the Court should do with those motions.

the Court to request a telephone conference concerning the dispute. The Court will seek to resolve the dispute during the telephone conference, and may enter appropriate orders on the basis of the telephone conference. The Court may order written briefing if it does not resolve the dispute during the telephone conference.[3] Parties shall not contact the Court concerning a discovery dispute without first seeking to resolve the matter through personal consultation and sincere effort as required by Local Rule of Civil Procedure 7.2(j).

C. Briefing Requirements. All memoranda filed with the Court shall comply with Local Rule of Civil Procedure 7.1(b) requiring 13 point font in text and footnotes. Citations in support of any assertion in the text shall be included in the text, not in footnotes.

D. Rule 34 Responses. Rule 34 responses shall comply with the amended Rule 34 to become effective on December 1, 2015.

Dated this 30th day of October, 2015.

David G. Campbell
United States District Judge

[3] The prohibition on "written discovery motions" includes any written materials delivered or faxed to the Court, including hand-delivered correspondence with attachments.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC **MASTER SHORT FORM COMPLAINT FOR DAMAGES FOR INDIVIDUAL CLAIMS**

Plaintiff(s) named below, for their Complaint against Defendants named below, incorporate the Master Complaint for Damages in MDL 2641 by reference (Doc.___). Plaintiff(s) further show the Court as follows:

1. Plaintiff/Deceased Party:

_____

2. Spousal Plaintiff/Deceased Party's spouse or other party making loss of consortium claim:

_____

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator):

_____

4. Plaintiff's/Deceased Party's state(s) [if more than one Plaintiff] of residence at the time of implant:

_____

GALLAGHER & KENNEDY, P.A.
2575 EAST CAMELBACK ROAD
PHOENIX, ARIZONA 85016-9225
(602) 530-8000

5. Plaintiff's/Deceased Party's state(s) [if more than one Plaintiff] of residence at the time of injury:

_____

6. Plaintiff's current state(s) [if more than one Plaintiff] of residence:

_____

7. District Court and Division in which venue would be proper absent direct filing:

_____

8. Defendants (check Defendants against whom Complaint is made):

□ C.R. Bard Inc.

□ Bard Peripheral Vascular, Inc.

9. Basis of Jurisdiction:

□ Diversity of Citizenship

□ Other: _____

a. Other allegations of jurisdiction and venue not expressed in Master Complaint:

_____

_____

_____

10. Defendants' Inferior Vena Cava Filter(s) about which Plaintiff(s) is making a claim (Check applicable Inferior Vena Cava Filter(s)):

□ Recovery® Vena Cava Filter

□ G2® Vena Cava Filter

- € G2® Express (G2®X) Vena Cava Filter
- € Eclipse® Vena Cava Filter
- € Meridian® Vena Cava Filter
- € Denali® Vena Cava Filter
- € Other: _____

11. Date of Implantation as to each product:

_____

_____

12. Counts in the Master Complaint brought by Plaintiff(s):

- □ Count I: Strict Products Liability – Manufacturing Defect
- □ Count II: Strict Products Liability – Information Defect (Failure to Warn)
- □ Count III: Strict Products Liability – Design Defect
- □ Count IV: Negligence - Design
- □ Count V: Negligence - Manufacture
- □ Count VI: Negligence – Failure to Recall/Retrofit
- □ Count VII: Negligence – Failure to Warn
- □ Count VIII: Negligent Misrepresentation
- □ Count IX: Negligence *Per Se*
- □ Count X: Breach of Express Warranty
- □ Count XI: Breach of Implied Warranty
- □ Count XII: Fraudulent Misrepresentation

□ Count XIII: Fraudulent Concealment

□ Count XIV: Violations of Applicable _____ (insert state) Law Prohibiting Consumer Fraud and Unfair and Deceptive Trade Practices

□ Count XV: Loss of Consortium

□ Count XVI: Wrongful Death

□ Count XVII: Survival

□ Punitive Damages

□ Other(s): _____ (please state the facts supporting this Count in the space immediately below)

_____

_____

_____

_____

_____

RESPECTFULLY SUBMITTED this ____ day of November, 2015.

GALLAGHER & KENNEDY, P.A.

By: */s/*
Robert W. Boatman
Mark S. O'Connor
Paul L. Stoller
Shannon L. Clark
C. Lincoln Combs
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Attorneys for Plaintiffs

I hereby certify that on this ____ day of November, 2015, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/

5131774

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. MDL 15-02641-PHX DGC

CASE MANAGEMENT ORDER NO. 4

(Master Complaint, Master Responsive Pleading, Use of Short Form Complaint, and Waiver of Service for Bard Defendants)

The parties have submitted a Master Long Form Complaint and Jury Demand (previously docketed as Doc. 303-1) and a Master Responsive Pleading (previously docketed as Doc. 303-3). The Court has reviewed these proposed pleadings, finds them sufficient, and directs the Clerk to file them as separate documents in the Court's docket.[1] The parties have also submitted a proposed Short Form Complaint, a copy of which is attached to this order. The Court also finds this proposed pleading to be sufficient.

IT IS ORDERED:

All allegations pled in the Master Complaint and all responses pled in the Master Responsive Pleading are deemed pled in any previously filed Complaint and Responsive Pleading in this MDL proceeding, except as expressly noted below. They are also deemed pled in any Short Form Complaint and Entry of Appearance filed after the entry of this

[1] The reference to "Federal Rule of Evidence 8" on the first page of the Master Complaint shall be deemed to be a reference to Federal Rule of Civil Procedure 8.

order, except that the Master Complaint applies only against the Defendant or Defendants identified in such future-filed Short Form Complaints.

The following cases will not be governed by the Master Complaint and Master Responsive Pleading, but will continue to be governed by the complaints (including any amended complaints) and answers filed in the various transferor courts prior to transfer:

Plaintiff	Original Jurisdiction
1. Cason, Pamela	GA – N.D. Ga. 1:12-cv-1288
2. Coker, Jennifer	GA – N.D. Ga. 1:13-cv-515
3. Conn, Charles	TX – S.D. Tex. 4:14-cv-298
4. Ebert, Melissa	PA – E.D. Pa. 5:12-cv-1253
5. Fox, Susan	TX – N.D. Tex. 3:14-cv-133
6. Henley, Angela	WI – E.D. Wis. 2:14-cv-59
7. Keen, Harry	PA – E.D. Pa. 5:13-cv-5361
8. Milton, Gary	GA – M.D. Ga. 5:14-cv-351
9. Mintz, Jessica	NY – E.D.N.Y. 2:14-v-4942
10. Ocasio, Denise	FL – M.D. Fla. 8:13-cv-1962

Plaintiff	Original Jurisdiction
11. Rivera (McClarty), Vicki	MI – E.D. Mich. 4:14-cv-13627
12. Smith, Erin	TX – E.D. Tex. 1:13-cv-633
13. Tillman, Lessie	FL – M.D. Fla. 3:13-cv-222

On or after **December 28, 2015**, any plaintiff whose case would be subject to transfer to MDL 2641 may file his or her case directly in this Court by using the Short Form Complaint. If such a case is filed in this Court without the use of the Short Form Complaint, Plaintiffs' Co-Lead Counsel shall promptly advise the filing party to file an amended complaint using the Short Form Complaint. If the filing party fails to do so, Plaintiffs' Co-Lead Counsel shall promptly notify the Court.

Defendants are not required to file answers to Short Form or Amended Short Form Complaints. An Entry of Appearance shall constitute a denial of all allegations in the Short Form or Amended Short Form Complaints except as herein provided, and an assertion of all defenses included in the Master Responsive Pleading. By filing an Entry of Appearance in response to a Short Form Complaint, in lieu of an answer, Defendants do not waive any defenses, including jurisdictional and service defenses.

Defendants shall have 60 days from the entry of this order to file any motion for failure of the Master Complaint to state a claim upon which relief may be granted pursuant to Rule 12(b)(6) and 12(h)(2), and Plaintiff's shall have 30 days to respond.

Civil actions in this MDL were transferred to this Court by the Judicial Panel on Multidistrict Litigation for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. Upon completion of the pretrial proceedings related to a civil action as determined by this Court, the case shall be transferred pursuant to 28 U.S.C. § 1404(a) or § 1406(a) to the District Court identified in the Short Form Complaint, provided the

parties choose not to waive *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). The fact that a case was filed directly in this District and MDL proceeding shall not constitute a determination by this Court that jurisdiction or venue are proper in this District, and shall not result in this Court being deemed the "transferor court" for purposes of this MDL. In addition, filing a Short Form Complaint in this District shall have no impact on the conflict of law rules to be applied to the case. Instead, the law of the jurisdiction where the case is ultimately transferred will govern any conflict of law. Prior to transfer, Defendants may object to the district specified in the Short Form Complaint, based on venue or jurisdiction (including a lack of personal jurisdiction based on *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014)), and propose an alternative jurisdiction for the Court's consideration.

Subject to the conditions set forth in this order, Defendant C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") waive service of process in cases filed in this Court using the Short Form Complaint and in which they are named as defendants and one or more IVC filter products either manufactured or distributed by Bard is alleged to be at issue. For such cases, Plaintiffs shall send a Short Form Complaint and a request for waiver of service pursuant to the provisions of Fed. R. Civ. P. 4 to Richard B. North, Jr. by email to richard.north@nelsonmullins.com; maria.turner@nelsonmullins.com; and matthew.lerner@nelsonmullins.com. Counsel for Bard shall return the signed waiver requests to the Court within the time permitted by Fed. R. Civ. P. 4. Plaintiffs submitting a request for waiver shall not seek to hold Bard in default for failure to timely answer or otherwise respond to a complaint in which service has been accomplished pursuant to the terms of this order without first giving Bard written notice of the alleged default and ten business days in which to cure any alleged default.

Prior to a Plaintiff's attorney filing a Short Form Complaint in this Court, that attorney must register for or already have a District of Arizona CM/ECF log-in name and password. If the Plaintiff's attorney does not already have a District of Arizona CM/ECF log-in name and password, that attorney **must** file the Short Form Complaint in paper

form with the Clerk of Court and simultaneously file an Application of Attorney for Admission to Practice Pro Hac Vice pursuant to LRCiv 83.1(b)(2) (including all necessary attachments and filing fee).

Dated this 17th day of December, 2015.

David G. Campbell
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC **MASTER SHORT FORM COMPLAINT FOR DAMAGES FOR INDIVIDUAL CLAIMS**

Plaintiff(s) named below, for their Complaint against Defendants named below, incorporate the Master Complaint for Damages in MDL 2641 by reference (Doc.___). Plaintiff(s) further show the Court as follows:

1. Plaintiff/Deceased Party:

_____

2. Spousal Plaintiff/Deceased Party's spouse or other party making loss of consortium claim:

_____

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator):

_____

4. Plaintiff's/Deceased Party's state(s) [if more than one Plaintiff] of residence at the time of implant:

_____

GALLAGHER & KENNEDY, P.A.
2575 EAST CAMELBACK ROAD
PHOENIX, ARIZONA 85016-9225
(602) 530-8000

5. Plaintiff's/Deceased Party's state(s) [if more than one Plaintiff] of residence at the time of injury:

_____

6. Plaintiff's current state(s) [if more than one Plaintiff] of residence:

_____

7. District Court and Division in which venue would be proper absent direct filing:

_____

8. Defendants (check Defendants against whom Complaint is made):

□ C.R. Bard Inc.

□ Bard Peripheral Vascular, Inc.

9. Basis of Jurisdiction:

□ Diversity of Citizenship

□ Other: _____

a. Other allegations of jurisdiction and venue not expressed in Master Complaint:

_____

_____

_____

10. Defendants' Inferior Vena Cava Filter(s) about which Plaintiff(s) is making a claim (Check applicable Inferior Vena Cava Filter(s)):

□ Recovery® Vena Cava Filter

□ G2® Vena Cava Filter

- € G2® Express (G2®X) Vena Cava Filter
- € Eclipse® Vena Cava Filter
- € Meridian® Vena Cava Filter
- € Denali® Vena Cava Filter
- € Other: _____

11. Date of Implantation as to each product:

_____

_____

12. Counts in the Master Complaint brought by Plaintiff(s):

- □ Count I: Strict Products Liability – Manufacturing Defect
- □ Count II: Strict Products Liability – Information Defect (Failure to Warn)
- □ Count III: Strict Products Liability – Design Defect
- □ Count IV: Negligence - Design
- □ Count V: Negligence - Manufacture
- □ Count VI: Negligence – Failure to Recall/Retrofit
- □ Count VII: Negligence – Failure to Warn
- □ Count VIII: Negligent Misrepresentation
- □ Count IX: Negligence *Per Se*
- □ Count X: Breach of Express Warranty
- □ Count XI: Breach of Implied Warranty
- □ Count XII: Fraudulent Misrepresentation

☐ Count XIII: Fraudulent Concealment

☐ Count XIV: Violations of Applicable _____ (insert state) Law Prohibiting Consumer Fraud and Unfair and Deceptive Trade Practices

☐ Count XV: Loss of Consortium

☐ Count XVI: Wrongful Death

☐ Count XVII: Survival

☐ Punitive Damages

☐ Other(s): _____ (please state the facts supporting this Count in the space immediately below)

_____

_____

_____

_____

_____

RESPECTFULLY SUBMITTED this ____ day of November, 2015.

GALLAGHER & KENNEDY, P.A.

By: */s/*
Robert W. Boatman
Mark S. O'Connor
Paul L. Stoller
Shannon L. Clark
C. Lincoln Combs
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Attorneys for Plaintiffs

I hereby certify that on this ____ day of November, 2015, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/

Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Robert W. Boatman (009619) - rwb@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Attorneys for Plaintiffs

GALLAGHER & KENNEDY, P.A.
2575 EAST CAMELBACK ROAD
PHOENIX, ARIZONA 85016-9225
(602) 530-8000

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC **MASTER COMPLAINT FOR DAMAGES FOR INDIVIDUAL CLAIMS**

Plaintiffs in this consolidated action, collectively and through the Plaintiffs' Steering Committee ("PSC") as duly authorized representatives of all Plaintiffs in MDL 2641, hereby file this Master Complaint for Damages for Individual Claims ("Master Complaint") against Defendants C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC. (collectively, "Bard" or "Defendants") in MDL 2641.

This Master Complaint is created for the convenience of the Court and all parties as a "long form" complaint giving notice, pursuant to Federal Rule of Evidence 8 and Case Management Order 2, of allegations that some or all Plaintiffs in cases consolidated in this MDL allege against Bard, whether those Plaintiffs' claims are for personal injury or wrongful

death, and whether brought by an individual person alleging injury or statutory or common law beneficiaries of claims for wrongful death of a Plaintiff or Plaintiffs' decedent.[1]

This Master Complaint does not necessarily include all claims asserted in all of the actions transferred to this Court, and it is not intended to consolidate for any purpose the separate claims of Plaintiffs herein. This Master Complaint also does not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, and no Plaintiff relinquishes the right to amend their individual complaints to seek any additional claims as discovery proceeds.

Accordingly, Plaintiffs in MDL No. 2641 allege as follows:

INTRODUCTORY ALLEGATIONS

1. Plaintiffs bring this action for personal injuries and/or wrongful death damages suffered by an injured or deceased party or parties as a direct and proximate result of an injured or deceased party being implanted with a defective and unreasonably dangerous Inferior Vena Cava ("IVC") filter medical device manufactured by Bard.

2. The subject IVC filters are part of Bard's IVC "retrievable" filter product line and include the following devices: Recovery®, G2®, G2®X (G2 Express®), Eclipse®, Meridian® and Denali® (for convenience, these devices will be referred to in this complaint under the generic term "Bard IVC Filters"). The term "Bard IVC Filters" also includes Bard's Recovery® Cone Removal System®.

[1] Which causes of actions and counts are asserted in individual actions and certain claimant- or claim-specific allegations will be conveyed to Defendants via individual "short form" complaints or profile forms as agreed upon by the parties.

3. Plaintiffs' claims for damages all relate to Bard's design, manufacture, sale, testing, marketing, labeling, advertising, promotion, and/or distribution of Bard IVC Filters.

4. The Bard IVC Filters that are the subject of this action all reached Plaintiffs and their physicians without substantial change in condition from the time they left Bard's possession.

5. Plaintiffs and their physicians used the Bard IVC Filters in the manner in which they were intended.

6. Bard is solely responsible for any alleged design, manufacture or informational defect Bard IVC Filters contain.

7. Bard does not allege that any other person or entity is comparatively at fault for any alleged design, manufacture, or informational defect Bard IVC Filters contain.

PARTIES

8. Plaintiffs are those persons and estates that have brought or will bring actions seeking wrongful death and/or personal injury damages caused by Bard IVC Filters. The identities of individual action plaintiffs will be identified in their "Short Form Complaint."

9. Plaintiffs are persons injured, killed, or otherwise harmed by Bard IVC Filters. Depending on the law applicable to a particular plaintiff or plaintiffs' claims, Plaintiffs may include deceased individuals and/or their spouses, children, parents, or personal representatives, as well as injured individuals and/or their spouses, children, parents, next friends, legal guardians, conservators, or other authorized representatives.

10. As a direct and proximate result of having Bard IVC Filters implanted in them, Plaintiffs named in their respective Short Form Complaints have suffered permanent and

continuous injuries and damages. The injuries suffered and damages sought by Plaintiffs (hereafter, "Injuries and Damages") may include, without limitation: wrongful death of a spouse, child, parent, or other legally-cognizable relationship; pain and suffering; bodily injuries of any type (including, without limitation, perforation of organs and venous structures, thromboembolic events, and cardiovascular injuries); disability; impairment; scarring; disfigurement; dismemberment; physical; emotional and psychological trauma; anxiety; diminished capacity; loss of consortium; hedonic damages; past medical expenses; future medical expenses; caregiving costs; lost wages; loss of earning capacity; and any other form of damages under the law of any forum which governs any individual case.

11. Defendant C.R. Bard, Inc. ("C.R. Bard") is a corporation duly organized and existing under the laws of the state of Delaware and has its principal place of business in New Jersey. Bard, at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Recovery®, G2®, G2®X (G2 Express®), Eclipse®, Meridian®, and Denali® Filter Systems to be implanted in patients throughout the United States including the State of Arizona and Plaintiffs' states of residence and/or injury.

12. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly-owned subsidiary corporation of Defendant C.R. Bard, with its principal place of business at 1625 West Third Street, Tempe, Arizona. BPV, at all times relevant to this action, designed, set specifications for, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Recovery®, G2®, G2®X(G2 Express®), Eclipse®, Meridian®, and Denali® Filter

Systems to be implanted in patients throughout the United States, including the State of Arizona and Plaintiffs' states of residence and/or injury.

13. There exists, and at all relevant times existed, a unity of interest in ownership between certain defendants and other defendants such that any individuality and separateness between the certain defendants has ceased and those defendants are the alter ego of the other certain defendants, and exerted control over those defendants.

14. Adherence to the fiction of the separate existence of these certain defendants as any entity distinct from other certain defendants would permit an abuse of the corporate privilege, sanction fraud, and promote injustice.

15. Plaintiffs are informed and believe, and thereon allege, that at all times herein mentioned each of the Defendants were the agent, servant, employee, and/or joint venturer of the other co-defendants, and at all said times each Defendant was acting in the full course, scope, and authority of said agency, service, employment, and/or joint venture.

16. "Bard" or "Defendants" includes any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind; their predecessors, successors, and assigns; their officers, directors, employees, agents, representatives; and any and all other persons acting on their behalf.

17. At all times relevant, Bard was engaged in the business of researching, designing, testing, developing, manufacturing, packaging, labeling, marketing, advertising, distributing, promoting, warranting, and selling in interstate commerce Bard IVC Filters, either directly or indirectly through third parties or related entities.

18. Bard develops, manufactures, sells, and distributes medical devices and surgical products throughout the United States and around the world, including Bard IVC Filters for use in various medical applications including endovascular cardiology.

19. Upon information and belief, at all relevant times, Defendants expected or should have expected that their acts would have consequences within the United States, including in the State of Arizona and in the states and territories identified in each Short Form Complaint, and said Defendants derived and continue to derive substantial revenue therefrom.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction under 28 U.S.C. § 1332 because Plaintiffs and Defendants are citizens of different states, the amount in controversy for each action exceeds seventy-five thousand dollars ($75,000.00) excluding interest and costs, and there is complete diversity of citizenship between each Plaintiff and Defendant.

21. This Court has personal jurisdiction under 28 U.S.C. § 1391, as BPV is domiciled in this District and all Defendants regularly conduct business in this State. Further, Defendants are present and doing business within this State and have continuous and systematic contacts in every state in the United States of America, including each Plaintiffs' states of residence.

22. Pursuant to the Transfer Order filed on August 17, 2015, it was determined:

> [T]he actions in this litigation involve common questions of fact, and that centralization in the District of Arizona will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. All actions involve common factual questions arising from allegations that defects in the design of Bard's retrievable inferior vena cava filters ("IVC filters") make them more likely to fracture, migrate, tilt, or perforate the inferior vena cava, causing injury. Centralization will eliminate duplicative discovery, avoid

inconsistent pretrial rulings (including with respect to discovery, privilege, and *Daubert* motion practice), and conserve the resources of the parties, their counsel and the judiciary.

23. Pursuant to the Transfer Order filed on August 17, 2015, cases are being transferred to The Honorable David G. Campbell in the United States District Court for the District of Arizona, Phoenix Division, as part of the IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION MDL 2641.

24. Pursuant to Case Management Order No. 2, federal cases against Bard relating to Bard IVC Filters may be directly filed in this District.

BACKGROUND

INFERIOR VENA CAVA FILTERS GENERALLY

25. IVC filters were first made commercially available to the medical community in the 1960s. Over the years, medical device manufacturers have introduced several different designs of IVC filters.

26. An IVC filter is a device that is designed to filter or "catch" blood clots that travel from the lower portions of the body to the heart and lungs. IVC filters were originally designed to be permanently implanted in the IVC.

27. The IVC is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, blood clots travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these blood clots develop in the deep leg veins, a condition called "deep vein thrombosis" or "DVT." Once blood clots reach the lungs, they are considered "pulmonary emboli" or "PE." Pulmonary emboli present risks to human health.

28. People at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe anticoagulant therapies such as medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE and who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolitic events.

29. As stated above, IVC filters have been on the market for decades and were permanent implants. However, use of these filters was limited primarily to patients who were contraindicated for anticoagulation therapy.

30. In order to increase sales of these devices, Bard sought to expand the market for prophylactic use among nontraditional patient populations that were temporarily at risk of developing blood clots.

31. Specifically, Bard targeted the bariatric, trauma, orthopedic and cancer patient population. Expansion to these new patient groups would triple sales and the first manufacturer to market would capture market share.

32. At the same time, Bard was aware that physicians developed interest in filter devices that could be easily removed after the risk of clotting in these new patient populations subsided. This too was an opportunity to gain market share in the lucrative IVC filter market.

33. Other manufacturers also saw this opportunity, triggering a race to market a device that provided physicians the option to retrieve the filter after the clot risk subsided.

34. Bard was the first medical device manufacturer to obtain FDA clearance for marketing a “retrievable” IVC filter (the Bard Recovery® filter) in July 2003.

35. This "clearance" was obtained despite lack of adequate testimony on the safety and efficacy of the new line of devices.

36. As shown below, Bard's retrievable IVC filters have been plagued with problems – all created by Bard itself – most notably, the absence of any evidence that the products were effective in preventing pulmonary embolism (the very condition the product was indicated to prevent).

37. Years after the implantation of retrievable filters into the bodies of patients, scientists began to study the effectiveness of the retrievable filters – studies that Bard itself had never done before placing the product on the market. As recently as October 2015, an expansive article published in the *Annals of Surgery* concerning trauma patients inserted with IVC filters concluded that IVC filters were not effective in preventing pulmonary emboli, and instead actually caused thrombi to occur.

38. Comparing the results of over 30,000 trauma patients who had not received IVC filters with those who had received them, the *Annals of Surgery* study published its alarming results:

- Almost twice the percentage of patients with IVC filters in the study died compared to those that had not received them.
- Over five times the relative number of patients with IVC filters developed DVTs.
- Over four times the relative percentage of patients with filters developed thromboemboli.

- Over twice the percentage of patients developed a pulmonary embolus – the very condition Bard told the FDA, physicians, and the public that its IVC Filters were designed to prevent.

39. This *Annals of Surgery* study – and many others referenced by it – now shows without any question that IVC filters are not only utterly ineffective but that they are themselves a health hazard.

THE RECOVERY® FILTER

A. Development and Regulatory Clearance of the Recovery® Filter

40. Bard has distributed and marketed the Simon Nitinol Filter ("SNF") device since 1992. The SNF is a permanent filter with no option to retrieve it after implantation.

41. The SNF was initially manufactured by a company known as Nitinol Medical Technologies. In late 1999, Bard worked with Nitinol on the redesign of the SNF in order to make it retrievable. On October 19, 2001, Bard purchased the rights to manufacture, market, and sell this new, redesigned product in development at the time. This product ultimately became the Recovery® filter.

42. Bard's purpose for making a retrievable IVC filter was to increase profits by expanding the overall IVC filter market and, in turn, Bard's percentage share of that market.

43. Bard engaged in an aggressive marketing campaign for the filter, despite negative clinical data.

44. On November 27, 2002, Bard bypassed the more onerous Food and Drug Administration's ("FDA's") approval process for new devices and obtained "clearance" under Section 510(k) of the Medical Device Amendments to the Food, Drug, and Cosmetic

Act to market the Recovery® filter as a *permanent* filter by claiming it was substantially similar in respect to safety, efficacy, design, and materials as the SNF.

45. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" (PMA) process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp*., which the court quoted from:

> A manufacturer can obtain an FDA finding of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food Drug and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to be 'substantially equivalent' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the agency under a PMA. *A pre-market notification submitted under 510(k) is thus entirely different from a PMA which must include data sufficient to demonstrate that the IVC Filters is safe and effective.*

376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original).

46. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k) process, observing:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. . . . The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in average of 20 hours. . . . As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed quickly."

518 U.S. 470, 478-79 (1996) (quoting Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

47. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with the drug . . . and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling . . . ." This obligation extends to post-market monitoring of adverse events/complaints.

48. In July 2003, through this 510(k) process, Bard obtained clearance from the FDA to market the Recovery® filter for optional retrieval.

49. Although Bard began aggressively marketing the Recovery® filter in 2003, full market release did not occur until January 2004.

50. Bard was aware that the Recovery® filter was also used extensively off-label, including for purely prophylactic reasons for trauma patients or patients with upcoming surgeries such as bariatric (weight loss) and orthopedic procedures.

51. The Recovery® filter consists of two (2) levels of six (6) radially distributed NITINOL (a nickel titanium alloy whose full name is Nickel Titanium Naval Ordinance Laboratory) struts that are designed to anchor the filter into the inferior vena cava and to catch any embolizing clots.

52. This filter has six short struts, which are commonly referred to as the "arms," and six long struts, which are commonly referred to as the "legs."

53. Each strut is held together by a single connection to a cap located at the top of the filter. According to the patent application filed for this device, the short struts are primarily for "centering" or "positioning" within the vena cava, and the long struts with attached hooks are designed primarily to prevent the device from migrating in response to "normal respiratory movement" or "pulmonary embolism."

54. The alloy NITINOL possesses "shape memory," meaning NITINOL will change shape according to changes in temperature, then retake its prior shape after returning to its initial temperature.

55. When placed in saline, the Recovery® filter's NITINOL struts become soft and can be straightened to allow delivery through a small-diameter catheter. The NITINOL struts then resume their original shape when warmed to body temperature in the vena cava.

56. The Recovery® filter is inserted via catheter guided by a physician (normally an interventional radiologist) through a blood vessel into the inferior vena cava. The Recovery® Filter is designed to be retrieved in a similar fashion.

57. According to the Instructions for Use of this medical device, only the Recovery® Cone System could be used to retrieve the Recovery® filter (as well as subsequent generations of Bard's IVC filters).

58. The Recovery® Cone System is an independent medical device requiring approval by the FDA under the pre-market approval process or, if a substantially equivalent medical device was already on the market, clearance by the FDA pursuant to the 510(k) application process.

59. Although Bard marketed and sold the Recovery® Cone System separately, it never sought or obtained approval or clearance from the FDA for this device.

60. Bard's sale of the Recovery® Cone System was, therefore, illegal.

61. Bard illegally sold the Recovery® Cone System in order to promote the Recovery® filter as having a retrieval option.

B. Post-Market Performance Revealed The IVC Filters Failed to Perform as Expected

62. Once placed on the market, Bard immediately became aware of numerous confirmed events where its Recovery® filter fractured, migrated, or perforated the vena cava, caused thrombus and clotting, and caused serious injury, including death.

63. Premarket and post-market clinical trials revealed that the Recovery® failed and caused serious risk of harm. In addition, peer-reviewed literature reflected that such filters actually increased the risk of patients developing thromboembolitic events.

64. Approximately a month after the full-scale launch of the Recovery® filter, on February 9, 2004, Bard received notice of the first death associated with this filter. The next day, a MAUDE analysis was performed which revealed that there had been at least two other migration-related adverse events reported to Bard in 2003.

65. MAUDE is a database maintained by the FDA to house medical device reports submitted by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such as health care providers and patients).

66. Instead of pulling the Recovery® filter off the market, Bard focused on public relations and protecting its brand and image. By February 12, 2004, Bard had formed a crisis

communication team and drafted at least four communiques to pass onto its sales force containing false information designed to be relayed to concerned doctors.

67. By April of 2004, at least three deaths had been reported to Bard. Yet again, instead of recalling its deadly device, Bard concealed this information from doctors and patients and hired the public relations firm Hill & Knowlton to address anticipated publicity that could affect stock prices and sales.

68. Bard made the decision to continue to market and sell the Recovery® filter until its next generation product, the G2® IVC filter, was cleared by the FDA.

69. The G2® filter, however, was not cleared for market until August 29, 2005.

70. Meanwhile, the death count escalated.

71. On July 12, 2004, C.R. Bard CEO Timothy Ring received an executive summary reporting that there were at least 12 filter migrations resulting in four deaths and at least 17 reports of filter fracture, six cases of which involved strut embolization to the heart.

72. This same report advised that fracture rates for the Recovery® filter exceed reported rates of other filters.

73. These events revealed, or should have revealed, to Bard that the Recovery® filter is prone to an unreasonably high risk of failure and patient injury following placement in the human body.

74. Bard also learned that the Recovery® filter failed to meet migration resistence testing specifications.

75. In addition, multiple early studies reported that the Recovery® filter has a fracture and migration rate ranging from 21% to 31.7%, rates that are substantially higher

compared to other IVC filters. More recently, fractures were reported to be as high as 40% after five and a half years from the date of implant.

76. Bard had clear evidence that the Recovery® filter was not substantially equivalent to the predecessor SNF, making the Recovery® filter adulterated and misbranded, requiring its immediate withdrawal from the market.

77. At least one Bard executive concluded the Recovery® filter posed an unreasonable risk of harm and required corrective action, including a recall.

78. Likewise, Bard's G2® filter was predicted to have fracture rates as high as 37.5% after five years from date of implant.

79. Subsequent Bard IVC Filter models, including the electropolished version of the G2® filter known as the Eclipse, only marginally increased fracture resistance.

80. When IVC filter fractures occur, shards of the filter or even the entire filter can travel to the heart, where they can cause cardiac tamponade, perforation of the atrial wall, myocardial infarction, and/or death.

81. Bard IVC Filters similarly pose a high risk of tilting and perforating the vena cava walls. When such tilting occurs, the filters can also perforate the adjacent aorta, duodenum, small bowel, spine, or ureter, which may lead to and, upon information and belief, already have led to retroperitoneal hematomas, small-bowel obstructions, extended periods of severe pain, and/or death.

82. The Adverse Event Reports ("AERs") associated with all IVC filters demonstrate that Bard IVC Filters are far more prone to failure then are other similar IVC

filters. A review of the FDA MAUDE database from the years 2004 through 2008 shows that Bard IVC Filters are responsible for the following percentages of all IVC filter AERs:

a. 50% of all adverse events;

b. 64% of all occurrences of migration of the IVC Filters;

c. 69% of all occurrences of vena cava wall perforation; and

d. 70% of all occurrences of filter fracture.

83. These failures were often associated with severe patient injuries such as:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain; and

f. Perforations of tissue, vessels and organs.

84. These failures and resulting injuries are attributable, in part, to the fact that the Bard IVC Filter design was unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

85. In addition to design defects, Bard IVC Filters suffer from manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of the filters.

86. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the Bard IVC Filters while in the body. In

particular, the Recovery® filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the filters. These exterior manufacturing defects render Bard IVC Filters too weak to withstand normal placement within the human body.

87. Bard was aware that Bard IVC Filters had substantially higher reported failure rates than all other IVC filters for fracture, perforation, migration, and death. For example:

a. On April 23, 2004, Bard's Corporate VP of Quality Assurance sent an email noting that the Recovery® filter's reported failure rates "did not look good compared to permanent filters" and promised to remove the filter from the market if its reported death rate became "significantly greater than the rest of the pack."

b. On July 9, 2004, a BPV safety analysis of reported failure rates determined that the Recovery® filter had a reported failure rate that was 28 times higher than all other IVC filters.

c. On December 17, 2004, analysis determined that the "[r]eports of death, filter migration (movement), IVC perforation, and filter fracture associated with the Recovery® filter were seen in the MAUDE database at reporting rates that were 4.6, 4.4, 4.1, and 5.3 times higher, respectively, than reporting rates for all other filters. . . . These deficiencies were all statistically significant . . . [and were] significantly higher than those for other removable filters."

d. By December 2004, according to BPV's own findings pursuant to its safety procedure, the Recovery® filter had so many reported failures that it was deemed not reasonably safe for human use and required "correction."

e. A BPV safety analysis from June 28, 2011, revealed that the Recovery® filter had a reported fracture rate 55 times higher than the SNF.

f. Whereas the Recovery® filter was reported to have caused over a dozen deaths by early 2005, the SNF has never — to Plaintiffs' knowledge — been reported as associated with a patient death.

C. Defendants Knew Why the Recovery® Filter Was Failing and Were Aware of Available Design Changes that Could Substantially Reduce Failures

88. Bard knew why the design changes made to the Recovery® filter were causing failures.

89. Bard was aware that the diameter of the leg hooks was a substantial factor in a filter's ability to resist migration and fatigue.

90. By reducing the diameter of the hooks on the Recovery® filter, Bard had reduced the device's ability to remain stable and not fracture.

91. Bard also reduced the leg span of the Recovery® filter from that of the SNF filter by 25%. As a result, Bard knew its retrievable IVC filters lacked a sufficient margin of safety to accommodate expansion of the vena cava (distension) after placement.

92. Bard was also aware that its failure to electropolish the wire material prior to distribution meant that Bard IVC Filters had surface damage that reduced their fatigue resistance.

93. Bard was also aware that the Recovery® filter had a high propensity to tilt and perforate the vena cava, which substantially increased the risk of fracture.

94. Bard was also aware that fatigue resistance could be increased by decreasing the sharpness of the angle of the wire struts where they exited the cap at the top of the IVC filters, and by chamfering (rounding or reducing the sharpness) of the cap edge against which the struts rubbed.

95. A few examples of Bard's awareness of the unreasonably dangerous problems with Bard IVC Filters include:

a. On June 18, 2003, BPV engineer Robert Carr sent an email noting that chamfering the edge of the cap would reduce the likelihood of fracture.

b. On March 16, 2004, a BPV engineer sent an email admitting that the surface damage seen on the Recovery® filter from the manufacturing process decreases fatigue resistance and that electropolishing increases fatigue resistance.

c. In an April 2004 meeting, BPV was warned by its physician consultants, Drs. Venbrux and Kaufman, that the migration resistance of the Recovery® filter needed to be raised from 50 mmHg to 140 mmHg. They further warned BPV that Bard's Recovery® filter was a "wimpy" filter and its radial force was inadequate to assure stability.

d. On May 5, 2004, a BPV engineer sent an email stating that adding a "chamfer" to the filter would "address the arm fracture issue."

e. On May 26, 2004, a BPV engineer sent an email stating that a proposed modified Recovery® filter design with a large chamfer lasted 50 bending cycles before breaking, whereas another proposed modified Recovery® filter with a small chamfer broke after ten bending cycles.

96. Prior to Plaintiffs being implanted with a Bard IVC Filter, Bard was aware of other design changes that could make the Recovery® filter substantially safer. In a report dated February 16, 2005, BPV describes the design changes to the Recovery® filter, which became known as the G2® Filter. The report states that the Recovery® filter has been modified to "to increase migration and fracture resistance, and to minimize the likelihood of leg twisting, appendage snagging, filter tilting, and caval perforation." The document goes on to describe the design modifications, which include:

a. Increased ground wire diameter of the hook from .0085" to .0105" in order to improve the fracture resistance of the hook and to improve the migration resistance of the filter.

b. The leg span has been increased from 32mm to 40mm in order to improve the ability of the filter to expand with a distending vena cava reducing risk of migration.

c. The total filter arm length has increased from 20mm to 25mm, enlarging the arm span from 30mm to 33mm to aid in filter centering.

d. An additional inward bend has been applied to the end of the filter arm in order to improve arm interaction with the vessel wall and to address caval perforations and appendage snagging.

e. The arc of filter arm, as it attaches to the sleeve, has been modified to have a smooth radial transition instead of sharp angle. This change was made in order to reduce the stress concentration generated by the sharp angle and thus improve fracture resistance in the area of the filter.

f. The report concludes that the design modifications have substantially reduced the risk of fracture.

97. Subsequent design changes only marginally improved product safety, but did not fully or adequately address the Bard IVC Filters' deadly defects.

98. Electropolishing was added to the Bard IVC Filters in 2010 to reduce the risk of fracture. Electropolishing implanted Nitinol IVC filters was the industry standard, and increased fatigue resistance by at least 25%, according to Bard's internal testing.

99. Additional anchors were added to the anchoring system on the filter in 2011, in what became known as the Meridian filter. The purpose of this improvement was to decrease the risk of tilting, which increases the risk of fracture and perforation, and reduce caudal migration.

100. Bard added penetration limiters with the introduction of Denali Filter in May 2013.

101. Penetration limiters are designed to reduce perforation and penetration of the vena cava.

D. Bard Misrepresented and Concealed the IVC Filters' Risks and Benefits

102. Despite knowing that the Recovery® filter was substantially more likely to fracture, migrate, tilt, and cause death than any other filter, Bard marketed its IVC filters as being safer and more effective than all other filters throughout the lifecycle of the product.

103. Bard further provided mandatory scripts to its Bard IVC filter sales force, which required the sales force to falsely tell physicians that the Recovery® filter was safe because it had the same reported failure rates as all other filters.

104. Even Bard's updated labeling in December 2004 downplayed and concealed the Recovery® filter's dangerous effects because it suggested fractures almost always cause no harm and that all filters had the same risk of failure.

105. Bard's updated labeling also downplayed the risk of harm by stating that serious injuries had only been "reported" when Bard knew such injuries had in fact occurred.

E. Bard Chose to Keep Selling an Unsafe IVC Filter and Lied to Its Own Sales Force to Ensure Market Share and Stock Prices

106. Instead of warning the public or withdrawing the IVC Filters from the market to fix the problems with its IVC filters, Defendants retained a public relations firm, opened a task force to prevent information from getting out to the public, and devised a plan to address the public if it did.

107. In 2004, Bard created a Crisis Communication Team that included members of Bard's upper level management, Bard's legal department, and independent consultants.

108. The Crisis Communication Team created a Crisis Communication Plan, which summarized Bard's motivation for withholding risk information from the public as follows:

> The proliferation of unfavorable press in top-tier media outlets can cause an onslaught of negative activity: a company's employee morale may suffer, stock prices may plummet, analysts may downgrade the affected company's rating, reputations may be ruined temporarily or even permanently. Extensive preparation is critical to help prevent the spread of damaging coverage.

109. In an April 2004 email, BPV consultant Dr. John Lehmann, a member of the Crisis Communication Team, advised Bard to conceal from the public Bard's information about the material risk of its IVC filters. Bard adopted his advice. His email states, among other things:

> Comparison with other filters is problematic in many ways, and we should avoid/downplay this as much as possible. When pressed, we simply paraphrase what was said in the Health Hazard. That "Estimates based on available data suggest that there is no significant difference in the rates of these complications between any of the IVC Filters currently marketed in the U.S., including the Recovery IVC Filters.
>
> ***
>
> I wouldn't raise this subject if at possible. It would be a most unusual reporter that will get this far. The testing data I saw in Arizona showed that although RF was certainly within the boundaries of IVC Filters tested, in larger veins it was near the bottom. I would avoid as much as possible getting into this subject, because I'm not sure others would agree with the conclusion that "Recovery Vena Cava Filter was just as or more resistant to migration than all retrievable and non-retrievable competitors.

110. Bard also made false representations and/omissions to the BPV sales force to keep them selling the IVC filters. Bard reassured the sales force that despite the failures with the Recovery® filter, the Bard IVC Filters were safe because they had the same failure rates as all other IVC filters.

111. By December 2004, BPV's own safety procedure deemed the Recovery® filter not reasonably safe for human use. Yet Bard continued to market and sell the Recovery® filter

into September 2005 and continued to allow its defective product to sit on shelves available to be implanted for an unknown period of time after September 2005.

112. Even after the G2® filter was launched in September 2005, Bard still failed to warn consumers of the increased risk posed by the Recovery® filter. Instead, Bard again chose to conceal information about the serious risks of substantial harm from the use of its defective product.

THE G2®, RECOVERY® G2 AND G2® EXPRESS FILTERS

113. On or about March 2, 2005, Bard submitted a Section 510(k) premarket notification of intent to market the G2® filter for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava. In doing so, Bard cited the Recovery® filter as the substantially equivalent predicate IVC filter, which was an inappropriate and illegal predicate device since it was being marketed while adulterated and misbranded for failing, among other things, to be as safe and effective as its predicate device, SNF. Bard stated that the only differences between the Recovery® filter and the G2® filter were primarily dimensional, and no material changes or additional components were added. It was considered by Bard the next generation of the Recovery® filter

114. On March 30, 2005, however, the FDA rejected this application unless Bard and BPV included "black box" warnings that read:

> Warning: The safety and effectiveness of the Recovery® Filter System in morbidly obese patients has not been established. There have been fatal device-related adverse events reported in this population.
>
> [and]
>
> [C]entral venous lines may cause the filters to move or fracture.

115. On April 19, 2005, prior to formally responding to the FDA's request to add a black box warning, BPV CEO Timothy Ring and C.R. Bard CEO John Weiland received an executive summary reporting that there were at least 34 migrations and 51 fractures associated with Bard IVC Filters.

116. This same report advised Bard executives that there were then nine deaths, six of which related to morbidly obese patients. Further, 18 of the 51 fractures resulted in fragments migrating to the heart.

117. On April 20, 2005, without alerting the FDA to the alarming information Bard executives had the day before, Bard submitted a letter in response to the FDA's request to add this black box warning stating that, "There is currently a statement in the IFU linking all of our complications to death."

118. On August 29, 2005, the FDA cleared the G2® filter for the same intended uses as the Recovery® filter, except that it was not cleared for retrievable use.[2] Contrary to the FDA's suggestion, no black box warning was added to warn the bariatric patient population of fatalities associated with the use of the filter.[3]

119. In September of 2005, Bard quietly and belatedly replaced the Recovery® filter on hospital shelves with the G2® filter. Bard either told doctors or led them to believe that the G2® was a new and improved version of the Recovery® filter with the same option to retrieve the filter after implant.

---

[2] The FDA did not clear the G2® filter to be used as a retrievable filter until January 15, 2008.

[3] A warning was eventually added to the IFU in October of 2009.

120. At the same time Bard was selling the G2® (then a permanent use filter without any retrievability option), Bard was also selling the SNF, which had the same indication for use with nearly zero adverse events.

121. Bard marketed the G2® filter as having "enhanced fracture resistance," "improved centering," and "increased migration resistance" without any data to back up these representations. Even if such data existed, Bard witnesses have testified that Bard would not share any such information with doctors if requested.

122. Moreover, as with its predecessor Recovery® filter, Bard failed to conduct adequate clinical and bench testing to ensure that the G2® filter would perform safely and effectively once implanted in the human body.

123. The G2® filter's design causes it to be of insufficient integrity and strength to withstand normal stresses within the human body so as to resist fracturing, migrating, and/or tilting, and/or perforating the inferior vena cava.

124. In addition to the same design defects as its predecessor device, the G2® filter suffers from the same manufacturing defects. These manufacturing defects include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of Bard IVC Filters. The presence of these draw markings and/or circumferential grinding markings further compromises the structural integrity of the G2® filter while *in vivo*.

125. In particular, the G2® filter is prone to fail at or near the location of draw markings/circumferential grinding markings on the struts of the IVC Filters.

126. Put simply, the G2® filter is not of sufficient strength to withstand normal placement within the human body. The presence of the aforementioned exterior manufacturing defects makes Bard IVC Filters more susceptible to fatigue, failure, and migration.

127. Similarly, although Bard rounded the chamfer at the edge of the cap of the G2® filter, it continued to fracture at that same location.

128. Thus, the G2® filter shares similar defects and health risks as the Recovery® filter.

129. Almost immediately upon the release of the G2® filter, Bard received notice of the same series of adverse events of migration, fracture, tilt, and perforation causing the same type of harm as the Recovery® filter. This time, however, a new and different adverse event emerged: the G2® filter would caudally (moving against blood flow) migrate in the direction toward the groin.

130. The G2® filter failures were again associated with reports of severe patient injuries such as:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Cardiac arrhythmia and other symptoms similar to myocardial infarction;

e. Severe and persistent pain; and

f. Perforations of tissue, vessels and organs.

131. Bard represents the fracture rate of the G2® filter to be 1.2%. Based upon a review of the data available in the public domain (including the FDA MAUDE database statistics and the published medical literature), this representation does not accurately reflect the true frequency of fractures for the G2® filter.

132. As with the Recovery® filter, Bard was aware of clinical data showing that the G2® filter was not the substantial equivalent of its predecessor SNF device, requiring immediate recall of the adulterated and misbranded product.

133. A review of the MAUDE database from the years 2004 through 2008 demonstrates that the Bard IVC Filters (including the G2® Filter) are responsible for the majority of all reported adverse events related to IVC filters.

134. On December 27, 2005, Bard's Medical Affairs Director sent an email questioning why Bard was even selling the modified version of the Recovery® filter, when Bard's SNF had virtually no complaints associated with it.

135. This further confirms the misbranded and adulterated nature of the device, requiring corrective action, including recall.

136. On January 15, 2008, the FDA allowed a retrievable option for the G2® filter, the G2 Express® filter. The G2 Express® filter (also known as the "G2®X") is identical in design to the G2® filter except that it has a hook at the top of the filters that allows it to be retrieved by snares, as well as Bard's Recovery Cone.

137. The G2®X filter contained no design modifications or improvements to alleviate the instability, structural integrity, and perforation problems that Bard knew to exist with the G2®X Filter via the 510(k) process.

THE ECLIPSE® FILTER

138. In a failed effort to resolve the complications associated with its previous filters, Bard designed the Eclipse® Vena Cava Filter as the next generation in its retrievable IVC filter family.

139. The Eclipse® filter was cleared by the FDA on January 14, 2010. The only design changes from the G2® family of filters to the Eclipse® filter was that the Eclipse® filter was electropolished.

140. According to Bard's internal testing, electropolishing supposedly increased fracture resistance by 25%. However, longitudinal studies published in peer-reviewed medical literature found that among 363 patients implanted with the Recovery® filter and 658 patients implanted with the G2® filter, the devices experienced fracture rates of 40% and 37.5%, respectively, after five and a half years. Thus, approximately 28.125% to 30% of Eclipse® filters would still be projected to fracture within five and a half years.

141. Without meaningful design changes, the Eclipse® filter continued to share several of the same design defects and complications associated with the Recovery® filter and G2® family of filters.

142. Soon after Bard launched the Eclipse® filter, it began receiving complaints and reports of injuries associated with the Eclipse® filter similar to those received with its predecessor filters.

143. Bard, however, knew and/or soon learned that the Eclipse® filter was not the substantial equivalent of the SNF, making this device also misbranded and adulterated, and subject to recall.

THE MERIDIAN® FILTER

144. The Meridian® filter was cleared by the FDA in August of 2011.

145. Bard represented to the FDA that the Meridian was substantially similar to the Eclipse® filter and could therefore be cleared via the less onerous 510(k) process.

146. Bard, however, knew and/or soon learned that the Meridian® filter was not the substantial equivalent of the SNF, making this device also misbranded and adulterated, and subject to recall.

147. The Meridian® filter system was the next-generation of Bard's retrievable or optional filters. The Meridian® filter is made of the same nickel-titanium alloy, NITINOL, as the Bard Recovery®, G2®, and Eclipse® filters.

148. The design of the Meridian is based on the Eclipse® filter, which, in turn, is based entirely on the G2® filter, which, in turn is based on the Recovery® Filter. Like the Eclipse®, the wires used in the Meridian® filter are electropolished prior to the forming of the filter. The only added feature to the Meridian® filter was a caudal anchoring system added in an attempt to reduce the prevalence of the filter caudal migrating toward the groin.

149. However, as seen with the Recovery®, G2®, and Eclipse® filters, soon after its introduction to the market reports surfaced that the Meridian® filters were fracturing, perforating, migrating, and/or tilting in the patients in which they were implanted.

150. The Meridian® filter was also plagued with the same manufacturing and design defects that were causing damage to the general public as Bard's predecessor retrievable filters.

THE DENALI® FILTER

151. The Denali® filter was cleared by the FDA on May 15, 2013. It is Bard's latest generation device in the IVC filter product line.

152. Bard represented to the FDA that the Denali® was substantially similar to the Eclipse® filter, again bypassing formal pre-market FDA approval and instead utilizing the 510(k) process.

153. The Denali® Filter is also made of NITINOL. Its design is based on the Eclipse® filter, which in turn, was based on Bard's predecessor filter line. Like the Eclipse®, the NITINOL wires used in the Denali® filter are electropolished prior to the forming of the filter. The added features to the Denali® Filter were cranial and caudal anchoring systems (to reduce the prevalence of the filter migration) and penetration limiters.

154. However, as seen with the Recovery®, G2®, G2X® (G2 Express®), and Eclipse® Filters, soon after its introduction to the market, reports were made that the Denali® filters were fracturing, perforating, migrating, and/or tilting in the patients in which they were implanted.

155. The Denali® filter was likewise plagued with the same manufacturing and design defects that were causing damage to the general public in Bard's predecessor retrievable filter family.

156. At all times material hereto from the design phase, testing, and manufacture of the Recovery® filter through the Denali® filter, Bard lacked a thorough understanding dynamics of caval anatomy that impacted testing methods.

157. At this time, all Bard IVC Filters contain the same or substantially similar defects resulting in the same or substantially similar mechanism of injury to Plaintiffs and their decedents.

158. At this time, all Bard IVC Filters are misbranded and adulterated by virtue of them failing to be the substantial equivalent of their predecessor devices, all of which were required to be as safe and effective as the original predicate device, the Simon Nitinol Filter, and none were/are, making them subject to corrective action, including recall, in the interest of patient safety. The use of each of these subject devices was inappropriate and illegal since each was being marketed while adulterated and misbranded for failing, among other things, to be as safe and effective as the originating predicate device, SNF.

159. At all relevant times, safer and more efficacious designs existed for this product, as well as reasonable treatment alternatives.

ESTOPPEL FROM PLEADING STATUTES OF LIMITATIONS OR REPOSE

160. Plaintiffs incorporate by reference all prior allegations.

161. Plaintiffs are within the applicable statute of limitations for their claims because Plaintiffs (and their healthcare professionals) did not discover, and could not reasonably discover, the defects and unreasonably dangerous condition of their Bard IVC Filters.

162. Plaintiffs' ignorance of the defective and unreasonably dangerous nature of the Bard IVC Filters, and the causal connection between these defects and Plaintiffs' injuries and damages, is due in large part to Bard's acts and omissions in fraudulently concealing information from the public and misrepresenting and/or downplaying the serious threat to public safety its products present.

163. In addition, Bard is estopped from relying on any statutes of limitation or repose by virtue of its unclean hands, acts of fraudulent concealment, affirmative misrepresentations and omissions.

164. Such conduct includes intentional concealment from Plaintiffs, Plaintiffs' prescribing health care professionals, and the general consuming public of material information that Bard IVC Filters had not been demonstrated to be safe or effective, and carried with them the risks and dangerous defects described above.

165. Bard had a duty to disclose the fact that Bard IVC Filters are not safe or effective, not as safe as other filters on the market, defective, and unreasonably dangerous, and that their implantation and use carried with it the serious risk of developing perforation, migration, tilting, and/or fracture.

COUNT I: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

166. Plaintiffs incorporate by reference all prior allegations.

167. Prior to, on, and after the date the Bard IVC Filters were implanted in Plaintiffs, Bard designed, distributed, manufactured, sold, and marketed Bard IVC Filters for use in the United States.

168. At all relevant times, Bard designed, distributed, manufactured, marketed, and sold Bard IVC Filters that were unreasonably dangerous, unsafe, and defective in manufacture when they left Bard's possession.

169. Upon information and belief, Bard IVC Filters contain a manufacturing defect, in that they differed from the manufacturer's design or specifications, or from other typical units of the same product line.

170. As a direct and proximate cause of Bard's design, manufacture, marketing, and sale of Bard IVC Filters prior to, on, and after the date Plaintiffs used the Bard IVC Filters, Plaintiffs suffered Injuries and Damages.

COUNT II: STRICT PRODUCTS LIABILITY – INFORMATION DEFECT

171. Plaintiffs incorporate by reference all prior allegations.

172. At all relevant times, Bard engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing and/or promoting, selling and/or distributing Bard IVC Filters and through that conduct has knowingly and intentionally placed Bard IVC Filters into the stream of commerce with full knowledge that they reach consumers such as Plaintiffs who would become implanted with them.

173. Bard did in fact test, develop, design, manufacture, package, label, market and/or promote, sell and/or distribute Bard IVC Filters to Plaintiffs, Plaintiffs' prescribing health care professionals, and the consuming public. Additionally, Bard expected that the Bard IVC Filters they were selling, distributing, supplying, manufacturing, and/or promoting to reach, and did in fact reach, prescribing health care professionals and consumers, including Plaintiffs and Plaintiffs' prescribing health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Bard.

174. The Bard IVC Filters had potential risks and side effects that were known or knowable to Bard by the use of scientific inquiry and information available before, at, and after the manufacture, distribution, and sale of the Bard IVC Filters.

175. Bard knew or should have known of the defective condition, characteristics, and risks associated with Bard IVC Filters. These defective conditions included, but were not

limited to: (1) Bard IVC Filters posed a significant and higher risk of failure than other similar IVC filters (fracture, migration, tilting, and perforation of the vena cava wall); (2) Bard IVC Filter failures result in serious injuries and death; and (3) certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of Bard IVC Filters.

176. Bard IVC Filters were in a defective and unsafe condition that was unreasonably and substantially dangerous to any user or consumer implanted with Bard IVC Filters, such as Plaintiffs, when used in an intended or reasonably foreseeable way.

177. The warnings and directions Bard provided with Bard IVC Filters failed to adequately warn of the potential risks and side effects of Bard IVC Filters.

178. These risks were known or were reasonably scientifically knowable to Bard, but not known or recognizable to ordinary consumers, such as Plaintiffs, or to Plaintiffs' treating doctors.

179. Bard IVC Filters were expected to and did reach Plaintiff without substantial change in their condition, labeling, or warnings as manufactured, distributed, and sold by Bard.

180. Additionally, Plaintiffs and Plaintiffs' physicians used Bard IVC Filters in the manner in which they were intended to be used, making such use reasonably foreseeable to Bard.

181. As a direct and proximate result of Bard's information defects, lack of sufficient instructions or warnings prior to, on, and after the date Plaintiffs used Bard IVC Filters, Plaintiffs suffered Injuries and Damages.

COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

182. Plaintiffs incorporate by reference all prior allegations.

183. At all relevant times, Bard designed, tested, distributed, manufactured, advertised, sold, marketed and otherwise placed into the stream of commerce Bard IVC Filters for use by consumers, such as Plaintiffs, in the United States.

184. Bard IVC Filters were expected to, and did, reach Bard's intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Bard.

185. At all times relevant, Bard IVC Filters were manufactured, designed and labeled in an unsafe, defective, and inherently dangerous condition which was dangerous for use by the public in general and Plaintiffs in particular.

186. Bard IVC Filters, as researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Bard were defective in design and formulation and unreasonably dangerous in that when they left the hands of Bard's manufacturers and/or suppliers, the foreseeable risks exceeded the alleged benefits associated with the use of Bard IVC Filters, and the devices were more dangerous than the ordinary customer would expect.

187. Physicians implanted Bard IVC Filters as instructed via the Instructions for Use and in a foreseeable manner as normally intended, recommend, promoted, and marketed by Bard.

188. Plaintiffs received and utilized Defendants' IVC Filters in a foreseeable manner as normally intended, recommended, promoted, and marketed by Bard.

189. At the time Bard placed its defective and unreasonably dangerous Bard IVC Filters into the stream of commerce commercially, technologically, and scientifically feasible alternative designs were attainable and available.

190. These alternative designs would have prevented the harm resulting in Plaintiffs' Injuries and Damages without substantially impairing the reasonably anticipated or intended function of Bard IVC Filters.

191. As a direct and proximate result of the defective and unreasonably dangerous condition of Bard IVC Filters, Plaintiffs suffered Injuries and Damages.

COUNT IV: NEGLIGENCE – DESIGN

192. Plaintiffs incorporate by reference all prior allegations.

193. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Bard IVC Filters, and their implantation in Plaintiffs, Bard was aware that Bard IVC Filters were designed and manufactured in a manner presenting:

a. An unreasonable risk of fracture of portions of the filters;

b. An unreasonable risk of migration of the filters and/or portions of the filters;

c. An unreasonable risk of filters tilting and/or perforating the vena cava wall; and

d. Insufficient strength or structural integrity to withstand normal placement within the human body.

194. At the time of the design, distribution, manufacture, advertising, sale, and marketing of Bard IVC Filters, and their implantation in Plaintiffs, Bard also was aware that Bard IVC Filters:

a. Would be used without inspection for defects;

b. Would be used by patients with special medical conditions such as those of the Plaintiffs;

c. Had previously caused serious bodily injury to its users with special medical conditions such as those of the Plaintiffs;

d. Had no established efficacy;

e. Were less efficient than the predicate SNF;

f. Would be implanted in patients where the risk outweighed any benefit or utility of the filters;

g. Contained instructions for use and warnings that were inadequate; and

h. Required retrieval (as to the Recovery® and G2® filters) by a device that was not approved or cleared by the FDA.

195. Bard had a duty to exercise due care and avoid unreasonable risk of harm to others in the design of Bard IVC Filters.

196. Bard breached these duties by, among other things:

a. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other IVC filters available for the same purpose;

c. Failing to perform reasonable pre- and post-market testing of Bard IVC Filters to determine whether or not the products were safe for their intended use;

d. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Bard IVC Filters so as to avoid the risk of serious harm associated with the use of Bard IVC Filters;

e. Advertising, marketing, promoting, and selling Bard IVC Filters for uses other than as approved and indicated in the products' labels;

f. Failing to establish an adequate quality assurance program used in the manufacturing of Bard IVC Filters; and

g. Failing to perform adequate evaluation and testing of Bard IVC Filters when such evaluation and testing would have revealed the propensity of Bard IVC Filters to cause injuries similar to those that Plaintiffs suffered.

197. As a direct and proximate result of the above-described negligence in design of Bard IVC Filters, Plaintiffs suffered Injuries and Damages.

COUNT V: NEGLIGENCE – MANUFACTURE

198. Plaintiffs incorporate by reference all prior allegations.

199. At all relevant times, Bard had a duty to exercise due care in the manufacturing of Bard IVC Filters.

200. Bard breached this duty by, among other things:

a. Failing to adopt manufacturing processes that would reduce the foreseeable risk of product failure;

b. Failing to use reasonable care in manufacturing the product and by producing a product that differed from their design or specifications or from other typical units from the same production line;

c. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Bard IVC Filters and their manufacturing process so as to avoid the risk of serious harm associated with the use of Bard IVC Filters; and

d. Failing to establish an adequate quality assurance program used in the manufacturing of the IVC Filters.

201. As a direct and proximate result of the above-described negligence in manufacture of Bard IVC Filters, Plaintiffs suffered Injuries and Damages.

COUNT VI: NEGLIGENCE – FAILURE TO RECALL/RETROFIT

202. Plaintiffs incorporate by reference all prior allegations.

203. At this time, all Bard IVC Filters are misbranded and adulterated by virtue of them failing to be the substantial equivalent of their predecessor device, making them subject to corrective action, including recall, in the interest of patient safety.

204. Prior to, on, and after the date of Plaintiffs' implantation with Bard IVC Filters, and at all relevant times, Bard knew or reasonably should have known that Bard IVC Filters and their warnings were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

205. Prior to, on, and after the date of Plaintiffs' implantation with Bard IVC Filters and at all relevant times thereafter, Bard became aware that the defects of Bard IVC Filters resulted in Bard IVC Filters causing injuries similar to those Plaintiffs suffered.

206. Reasonable manufacturers and distributors under the same or similar circumstances would have recalled or retrofitted Bard IVC Filters, and would thereby have avoided and prevented harm to many patients, including Plaintiffs.

207. In light of this information and Bard's knowledge described above, Bard had a duty to recall and/or retrofit Bard IVC Filters.

208. Bard breached its duty to recall and/or retrofit Bard IVC Filters.

209. As a direct and proximate result of Bard's negligent failure to recall or retrofit, Plaintiffs suffered Injuries and Damages.

COUNT VII: NEGLIGENCE – FAILURE TO WARN

210. Plaintiffs incorporate by reference all prior allegations.

211. At all relevant times, Bard knew or should have known that Bard IVC Filters were defective and dangerous or were likely to be dangerous when used in a reasonably foreseeable manner.

212. Such danger included the propensity of Bard IVC Filters to cause injuries and death similar to those suffered by Plaintiffs.

213. At all relevant times, Bard also knew or reasonably should have known that the users of Bard IVC Filters, including Plaintiffs, would not realize or discover on their own the dangers presented by Bard IVC Filters.

214. Reasonable manufacturers and reasonable distributors, under the same or similar circumstances as those of Bard prior to, on, and after the date of Plaintiffs' use of Bard IVC Filters, would have warned of the dangers presented by Bard IVC Filters, or instructed on the safe use of Bard IVC Filters.

215. Prior to, on, and after the date of Plaintiffs' use of the IVC Filters, Bard had a duty to adequately warn of the dangers presented by Bard IVC Filters and/or instruct on the safe use of Bard IVC Filters.

216. Bard breached these duties by failing to provide adequate warnings to Plaintiffs communicating the information and dangers described above and/or providing instruction for safe use of Bard IVC Filters.

217. As a direct and proximate result of Bard's negligent failure to warn, Plaintiffs suffered Injuries and Damages.

COUNT VIII: NEGLIGENT MISREPRESENTATION

218. Plaintiffs incorporate by reference all prior allegations.

219. Prior to, on, and after the dates during which Plaintiff was implanted with the IVC Filters, Bard negligently and carelessly represented to Plaintiffs, Plaintiffs' treating physicians, and the general public that Bard IVC Filters were safe, fit, and effective for use.

220. These representations were untrue.

221. Bard owed a duty in all of its undertakings, including the dissemination of information concerning its IVC filters, to exercise reasonable care to ensure that it did not in those undertakings create unreasonable risks of personal injury to others.

222. Bard disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of Bard IVC Filters with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use Bard IVC Filters.

223. Bard, as medical device designers, manufacturers, sellers, promoters and/or distributors, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using Bard IVC Filters, would rely upon information disseminated and marketed by Bard to them regarding the Bard IVC Filters.

224. Bard failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Bard IVC Filters was accurate, complete, and not misleading and, as a result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiffs.

225. Bard, as designers, manufacturers, sellers, promoters, and/or distributors, also knew or reasonably should have known that patients receiving Bard IVC Filters as recommended by health care professionals in reliance upon information disseminated by Bard as the manufacturer/distributor of Bard IVC Filters would be placed in peril of developing the

serious, life-threatening, and life-long injuries including, but not limited to, tilting, migration, perforation, fracture, lack of efficacy, and increased risk of the development of blood clots, if the information disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

226. Bard had a duty to promptly correct material misstatements it knew others were relying upon in making healthcare decisions.

227. Bard failed in each of these duties by misrepresenting to Plaintiffs and the medical community the safety and efficacy of Bard IVC Filters and failing to correct known misstatements and misrepresentations.

228. As a direct and proximate result of Bard's negligent misrepresentations, Plaintiffs suffered Injuries and Damages.

COUNT IX: NEGLIGENCE *PER SE*

(Violations of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

229. Plaintiffs incorporate by reference all prior allegations.

230. At all times herein mentioned, Bard was subject to a variety of federal, state, and local laws, rules, regulations and ordinances, including the Federal Food, Drug and Cosmetic Act ("FFDCA") and its applicable regulations, concerning the manufacture, design, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning, and post-sale warning and other communications of the risks and dangers of Bard IVC Filters.

231. By reason of its conduct as alleged herein, Bard violated provisions of statutes and regulations, including but not limited to:

a. FFDCA, 21 U.S.C. §§331 and 352, by misbranding Bard IVC Filters;

b. FFDCA, 21 U.S.C. § 321, by making statements and/or representations via word, design, device, or any combination thereof failing to reveal material facts with respect to the consequences that may result from the use of Bard IVC Filters to which the labeling and advertising relates;

c. 21 C.F.R. § 1.21, by misleading its consumers and patients by concealing material facts in light of representations made regarding safety and efficacy of its Bard IVC Filters;

d. 21 C.F.R. § 801, by mislabeling Bard IVC Filters as to safety and effectiveness of its products and by failing to update its label to reflect post-marketing evidence that Bard IVC Filters were associated with an increased risk of injuries due to tilting, fracture, migration and perforation;

e. 21 C.F.R. §§801.109 and 801.4 by learning that Bard IVC Filters were adulterated and misbranded and failing to correct and recall the devices.

f. 21 C.F.R. § 803, by not maintaining accurate medical device reports regarding adverse events of tilting, fracture, migration and perforation and/or misreporting these adverse events maintained via the medical device reporting system;

g. 21 C.F.R. § 807, by failing to notify the FDA and/or the consuming public when its Bard IVC Filters were no longer substantially equivalent

with regard to safety and efficacy with regard to post-marketing adverse events and safety signals;

h. 21 C.F.R. § 820, by failing to maintain adequate quality systems regulation including, but not limited to, instituting effective corrective and preventative actions;

i. 21 CFR 201.128, by promoting each of their subject devices off-label and for conditions, purposes and uses beyond their labeled and intended uses; and

j. 210 CFR 801.4, by their knowledge of off-label uses of their devices for unintended and unlabeled conditions, purposes and uses, and failing as required to provide adequate labeling which accords with such unlabeled and unintended uses.

232. These statutes, rules and regulations, along with those listed in Count XIV, are designed to protect the health, safety, and well-being of consumers like Plaintiffs.

233. Bard's violation of these statutes, rules and regulations, as well as those detailed in Count XIV, constitutes negligence *per se*.

234. As a direct and proximate result of Bard's negligence *per se*, Plaintiffs suffered Injuries and Damages.

COUNT X: BREACH OF EXPRESS WARRANTY

235. Plaintiffs incorporate by reference all prior allegations.

236. Plaintiffs, though their medical providers, purchased Bard IVC Filters from Bard.

237. At all relevant times, Bard was a merchant of goods of the kind including medical devices and vena cava filters (i.e, Bard IVC Filters).

238. At the time and place of sale, distribution, and supply of Bard IVC Filters to Plaintiffs (and to other consumer and the medical community), Bard expressly represented and warranted that Bard IVC Filters were safe; that they were well-tolerated, efficacious, fit for their intended purpose, and of marketable quality; that they did not produce any unwarned-of dangerous side effects; and that they was adequately tested.

239. At the time of Plaintiffs' purchase from Defendants, Bard IVC Filters were not in a merchantable condition, and Bard breached its expressed warranties, in that Bard IVC Filters:

a. Were designed in such a manner so as to be prone to an unreasonably high incidence of fracture, perforation of vessels and organs, and/or migration;

b. Were designed in such a manner so as to result in a unreasonably high incidence of injury to the vessels and organs of its purchaser;

c. Were manufactured in such a manner that the exterior surface of the filter was inadequately, improperly, and inappropriately constituted, causing the device to weaken and fail;

d. Were unable to be removed at any time during a person's life;

e. Were not efficacious in the prevention of pulmonary emboli;

f. Carried a risk of use outweighed any benefit; and

g. Were not self-centering.

240. As a direct and proximate result of Bard's breach of express warranty, Plaintiffs suffered Injuries and Damages.

COUNT XI: BREACH OF IMPLIED WARRANTY

241. Plaintiffs incorporate by reference all prior allegations.

242. Bard impliedly warranted that Bard IVC Filters were of merchantable quality and safe and fit for the use for which Bard intended them, and Plaintiffs in fact used them.

243. Bard breached its implied warranties by:

a. Failing to provide adequate instruction that a manufacturer exercising reasonable care would have provided concerning the likelihood that Bard IVC Filters would cause harm;

b. Manufacturing and/or selling Bard IVC Filters when those filters did not conform to representations made by Bard when they left Bard's control;

c. Manufacturing and/or selling Bard IVC Filters that were more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner;

d. Manufacturing and/or selling Bard IVC Filters that carried foreseeable risks associated with the Bard IVC Filter design or formulation which exceeded the benefits associated with that design;

e. Manufacturing and/or selling Bard IVC Filters when they deviated in a material way from the design specifications, formulas, or performance standards or from otherwise identical units manufactured to the same design specifications, formulas, or performance standards; and

f. Impliedly representing that its filters would be effective in the prevention of pulmonary emboli.

244. As a direct and proximate result of Bard's breach of its implied warranty, Plaintiffs have suffered Injuries and Damages.

COUNT XII: FRAUDULENT MISREPRESENTATION

245. Plaintiffs incorporate by reference all prior allegations.

246. At all times relevant to this cause, and as detailed above, Bard intentionally provided Plaintiffs, Plaintiffs' physicians, the medical community, and the public at large with false or inaccurate information. Bard also omitted material information concerning Bard IVC Filters, including, but not limited to, misrepresentations regarding the following topics:

a. The safety of the Bard IVC Filters;

b. The efficacy of the Bard IVC Filters;

c. The rate of failure of the Bard IVC Filters;

d. The pre-market testing of the Bard IVC Filters;

e. The approved uses of the Bard IVC Filters; and

f. The ability to retrieve the device at any time over a person's life.

247. The information Bard distributed to the public, the medical community, and Plaintiffs was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives.

248. These materials contained false and misleading material representations, which included: that Bard IVC Filters were safe and fit when used for their intended purpose or in a

reasonably foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings; and that they were adequately tested to withstand normal placement within the human body.

249. Bard made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and a warning document that was included in the package of Bard IVC Filters that were implanted in Plaintiffs.

250. Bard's intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiffs' health care providers; to gain the confidence of the public and the medical community, including Plaintiffs' health care providers; to falsely assure the public and the medical community of the quality of Bard IVC Filters and their fitness for use; and to induce the public and the medical community, including Plaintiffs' healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use Bard IVC Filters, all in reliance on Bard's misrepresentations.

251. The foregoing representations and omissions by Bard were false.

252. Bard IVC Filters are not safe, fit, and effective for human use in their intended and reasonably foreseeable manner.

253. Further, the use of Bard IVC Filters is hazardous to the users' health, and Bard IVC Filters have a serious propensity to cause users to suffer serious injuries, including without limitation the injuries Plaintiffs suffered.

254. Finally, Bard IVC Filters have a statistically significant higher rate of failure and injury than do other comparable IVC filters.

255. In reliance upon the false and negligent misrepresentations and omissions made by Bard, Plaintiffs and Plaintiffs' health care providers were induced to, and did use Bard IVC Filters, thereby causing Plaintiffs to sustain severe and permanent personal injuries and death.

256. Bard knew and had reason to know that Plaintiffs, Plaintiffs' health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Bard, and would not have prescribed and implanted Bard IVC Filters if the true facts regarding Bard IVC Filters had not been concealed and misrepresented by Bard.

257. Bard had sole access to material facts concerning the defective nature of the products and their propensities to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who were implanted with Bard IVC Filters.

258. At the time Bard failed to disclose and intentionally misrepresented the foregoing facts, and at the time Plaintiffs used Bard IVC Filters, Plaintiff and Plaintiffs' health care providers were unaware of Bard's misrepresentations and omissions.

259. As a direct and proximate result of Bard's fraudulent misrepresentations, Plaintiffs suffered Injuries and Damages.

COUNT XIII: FRAUDULENT CONCEALMENT

260. Plaintiffs incorporate by reference all prior allegations.

261. In marketing and selling Bard IVC Filters, Bard concealed material facts from Plaintiffs and Plaintiffs' healthcare providers.

262. These concealed material facts include, but are not limited to:

a. Bard IVC Filters were unsafe and not fit when used for their intended purpose or in a reasonably foreseeable manner;

b. Bard IVC Filters posed dangerous health risks in excess of those associated with the use of other similar IVC filters;

c. That there were additional side effects related to implantation and use of Bard IVC Filters that were not accurately and completely reflected in the warnings associated with Bard IVC Filters; and

d. That Bard IVC Filters were not adequately tested to withstand normal placement within the human body.

263. Plaintiff and Plaintiffs' healthcare providers were not aware of these and other facts concealed by Bard.

264. In concealing these and other facts, Bard intended to deceive Plaintiffs and Plaintiffs' healthcare providers.

265. Plaintiffs and Plaintiffs' healthcare providers were ignorant of and could not reasonably discover the facts Bard fraudulently concealed and reasonably and justifiably relied on Bard's representations concerning the supposed safety and efficacy of Bard IVC Filters.

266. As a direct and proximate result of Defendants' fraudulent concealment of material facts, Plaintiffs suffered Injuries and Damages.

COUNT XIV: VIOLATIONS OF APPLICABLE STATE LAW PROHIBITING CONSUMER FRAUD AND UNFAIR DECEPTIVE TRADE PRACTICES

267. Plaintiffs incorporate by reference all prior allegations.

268. Bard had a statutory duty to refrain from unfair or deceptive acts or practices in the sale and promotion of Bard IVC Filters.

269. Bard knowingly, deliberately, willfully and/or wantonly engaged in unfair, unconscionable, deceptive, fraudulent, and misleading acts or practices in violation of all states' consumer protection laws identified below.

270. Through its false, untrue, and misleading promotion of Bard IVC Filters, Bard induced Plaintiffs to purchase and/or pay for the purchase of Bard IVC Filters.

271. Bard misrepresented the alleged benefits and characteristics of Bard IVC Filters; suppressed, omitted, concealed, and failed to disclose material information concerning known adverse effects of Bard IVC Filters; misrepresented the quality and efficacy of Bard IVC Filters as compared to much lower-cost alternatives; misrepresented and advertised that Bard IVC Filters were of a particular standard, quality, or grade that they were not; misrepresented Bard IVC Filters in such a manner that later, on disclosure of the true facts, there was a likelihood that Plaintiffs would have opted for an alternative IVC filter or method of preventing pulmonary emboli.

272. Bard's conduct created a likelihood of, and in fact caused, confusion and misunderstanding.

273. Bard's conduct misled, deceived, and damaged Plaintiffs, and Bard's fraudulent, misleading, and deceptive conduct was perpetrated with an intent that Plaintiffs rely on said conduct by purchasing and/or paying for purchases of Bard IVC Filters.

274. Moreover, Bard knowingly took advantage of Plaintiffs, who were unable to protect their own interests due to ignorance of the harmful adverse effects of Bard IVC Filters.

275. Bard's conduct was willful, outrageous, immoral, unethical, oppressive, unscrupulous, unconscionable, and substantially injurious to Plaintiffs and offends the public conscience.

276. Plaintiffs purchased Bard's IVC Filters primarily for personal, family, or household purposes.

277. As a result of Bard's violative conduct in each of the Plaintiffs' respective states, Plaintiffs purchased and/or paid for purchases of Bard IVC Filters that were not made for resale.

278. Bard engaged in unfair competition or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq*.

279. Bard engaged in unfair competition or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq*.

280. Bard engaged in unfair competition or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq*.

281. Bard engaged in unfair competition or deceptive acts or practices in violation of Cal. Civ. Code § 1770, *et seq.* (the "Consumer Legal Remedies Act"), and Cal. Bus. & Prof. Code § 17200, *et seq.* and § 17500, *et seq*.

282. Bard engaged in unfair competition or deceptive acts or practices in violation of Colo. Rev. Stat. § 6-1-105, *et seq*.

283. Bard engaged in unfair competition or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110b, *et seq*.

284. Bard engaged in unfair competition or deceptive acts or practices in violation of D.C. Code Ann. § 28-3901, *et seq*.

285. Bard engaged in unfair competition or deceptive acts or practices in violation of 6 Del. Code Ann. § 2513, *et seq*.

286. Bard engaged in unfair competition or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.

287. Bard engaged in unfair competition or deceptive acts or practices in violation of Haw. Rev. Stat. § 480, *et seq*.

288. Bard engaged in unfair competition or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.

289. Bard engaged in unfair competition or deceptive acts or practices in violation of 815 Illinois L.C.S. §§ 505/2, 510/2, *et seq*.

290. Bard engaged in unfair competition or deceptive acts or practices in violation of Ind. Code § 24-5-0.5, *et seq*.

291. Bard engaged in unfair competition or deceptive acts or practices in violation of Kan. Stat. Ann. § 50-623, *et seq*.

292. Bard engaged in unfair competition or deceptive acts or practices in violation of KRS § 367.170, *et seq*.

293. Bard engaged in unfair competition or deceptive acts or practices in violation of 5 Me. Rev. Stat. Ann. § 207, *et seq*.

294. Bard engaged in unfair competition or deceptive acts or practices in violation of Md. Code, Commercial Law, § 13-301, *et seq*.

295. Bard engaged in unfair competition or deceptive acts or practices in violation of Mass. Gen. Laws Ch. 93A § 1, *et seq*.

296. Bard engaged in unfair competition or deceptive acts or practices in violation of M.C.L.A. § 445.901, *et seq*.

297. Bard engaged in unfair competition or deceptive acts or practices in violation of M.S.A. § 325F.69, *et seq.* and M.S.A. § 325D.44, *et seq.*

298. Bard engaged in unfair competition or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-5.

299. Bard engaged in unfair competition or deceptive acts or practices in violation of Missouri V.A.M.S. § 407.020, *et seq*.

300. Bard engaged in unfair competition or deceptive acts or practices in violation of Neb. Rev. St. § 59-1602, *et seq*.

301. Bard engaged in unfair competition or deceptive acts or practices in violation of Nev. Rev. Stat. §§ 41.600, 598.0903, *et seq*.

302. Bard engaged in unfair competition or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq*.

303. Bard engaged in unfair competition or deceptive acts or practices in violation of N.J. Stat. Ann. § 56:8-1, *et seq*.

304. Bard engaged in unfair competition or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq*.

305. Bard engaged in unfair competition or deceptive acts or practices in violation of N.Y. Gen. Bus. Law § 349, *et seq.*

306. Bard engaged in unfair competition or deceptive acts or practices in violation of N.C. Gen. Stat. Ann. § 75-1.1, *et seq.*

307. Bard engaged in unfair competition or deceptive acts or practices in violation of N.D.C.C. § 51-15-02, *et seq.*

308. Bard has engaged in unfair competition or deceptive acts or practices in violation of Ohio Rev. Code. Ann. § 1345.01, *et seq*.

309. Bard engaged in unfair competition or deceptive acts or practices in violation of 15 Okla. St. Ann. §§ 751-753, *et seq*.

310. Bard engaged in unfair competition or deceptive acts or practices in violation of Oregon Revised Statutes § 646.605, *et seq*.

311. Bard engaged in unfair competition or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq*.

312. Bard engaged in unfair competition or deceptive acts or practices in violation of R.I. Gen. Laws § 6-13.1-1, *et seq*.

313. Bard engaged in unfair competition or deceptive acts or practices in violation of S.D. Code Laws § 37-24-1, *et seq*.

314. Bard engaged in unfair competition or deceptive acts or practices in violation of Tenn. Code Ann. § 47-18-104, *et seq*.

315. Bard engaged in unfair competition or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq*.

316. Bard engaged in unfair competition or deceptive acts or practices in violation of Utah Code § 13-11-1, *et seq*.

317. Bard engaged in unfair competition or deceptive acts or practices in violation of 9 Vt. Stat. § 2451, *et seq*.

318. Bard engaged in unfair competition or deceptive acts or practices in violation of Va. Code § 59.1-200, *et seq*.

319. Bard engaged in unfair competition or deceptive acts or practices in violation of Wash. Rev. Code § 19.86.010, *et seq*.

320. Bard engaged in unfair competition or deceptive acts or practices in violation of W.Va. Code § 46A-6-101, *et seq*.

321. Bard engaged in unfair competition or deceptive acts or practices in violation of Wis. Stat. § 100.18, *et seq*.

322. Bard engaged in unfair competition or deceptive acts or practices in violation of Wy. Stat. § 40-12-101, *et seq*.

323. As a direct and proximate result of Bard's violations of these statutes, Plaintiffs suffered Injuries and Damages and seek all available damages under each state's law.

COUNT XV: LOSS OF CONSORTIUM

324. Plaintiffs incorporate by reference all prior allegations.

325. At all times relevant hereto, Plaintiffs' spouses ("Spouse Plaintiffs") and/or family members ("Family Member Plaintiffs") and/or domestic partners ("Domestic Partner Plaintiffs") have suffered injuries and losses as a result of Plaintiffs' injuries.

326. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs and/or Domestic Partner Plaintiffs have necessarily paid and have become liable to

pay for medical aid, treatment, and medications, and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

327. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs and/or Domestic Partner Plaintiffs have suffered and will continue to suffer the loss of their loved ones' support, companionship, services, society, love, and affection due to Bard IVC Filter injury.

328. For all Spouse Plaintiffs, Plaintiffs allege their marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

329. Spouse Plaintiffs and/or Family Member Plaintiffs and/or Domestic Partner Plaintiffs have suffered great emotional pain and mental anguish.

330. As a direct and proximate result of Bard's misconduct, Spouse Plaintiffs and/or Family Member Plaintiffs and/or Domestic Partner Plaintiffs have sustained Injuries and Damages.

COUNT XVI: WRONGFUL DEATH

331. Plaintiffs incorporate by reference all prior allegations.

332. Plaintiffs' decedents died as a direct and proximate result of Bard's misconduct as alleged herein, resulting in Plaintiffs' decedent's use of Bard IVC Filters.

333. Plaintiffs' decedents are survived by various family members, named and unnamed.

334. As a direct and proximate result of the acts and/or omissions of Bard, Plaintiffs' decedents' heirs and family have been deprived of his/her future aid, income, assistance,

services, companionship, society, affection and financial support, and Plaintiffs have suffered Injuries and Damages.

335. The representatives or administrators of Plaintiffs' decedents' estates bring these claims on behalf of the decedents' lawful heirs for the decedents' wrongful death where appropriate and authorized under relevant state law.

COUNT XVII: SURVIVAL

336. Plaintiffs incorporate by reference all prior allegations.

337. As a direct and proximate result of Bard's misconduct, Plaintiffs' decedents suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of enjoyment of life, medical expenses, loss of earnings and loss of earning capacity prior to Plaintiffs' decedents' deaths.

338. Where authorized under relevant state law, Plaintiffs and/or the appropriate authorized entity seek all damages the decedents suffered as a result of Bard IVC Filter injuries prior to death.

PUNITIVE DAMAGES ALLEGATIONS

339. Plaintiffs incorporate by reference all prior allegations.

340. At all times material hereto, Bard knew or should have known that Bard IVC Filters were unreasonably dangerous with respect to the risk of tilt, fracture, migration and/or perforation.

341. At all times material hereto, Bard attempted to misrepresent and did knowingly misrepresent facts concerning the safety of Bard IVC Filters.

342. Bard's misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiffs' physicians, concerning the safety of its Bard IVC Filters.

343. Bard's conduct, alleged throughout this Master Complaint, was willful, wanton, and undertaken with a conscious indifference and disregard to the consequences that consumers of their products faced, including Plaintiffs and their decedents.

344. At all times material hereto, Bard knew and recklessly disregarded the fact that Bard IVC Filters have an unreasonably high rate of tilt, fracture, migration, and/or perforation.

345. Notwithstanding the foregoing, Bard continued to market Bard IVC Filters aggressively to consumers, including Plaintiffs, without disclosing the aforesaid side effects.

346. Bard knew of its Bard IVC Filters' lack of warnings regarding the risk of fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to disclose that risk and continued to market, distribute, and sell its filters without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in conscious disregard of the foreseeable harm caused by Bard IVC Filters.

347. Bard's intentional and/or reckless failure to disclose information deprived Plaintiffs' physicians of necessary information to enable them to weigh the true risks of using Bard IVC Filters against its benefits.

348. Bard's conduct is reprehensible, evidencing an evil hand guided by an evil mind and was undertaken for pecuniary gain in reckless and conscious disregard for the substantial risk of death and physical injury to consumers, including Plaintiffs and their decedents.

349. Such conduct justifies an award of punitive or exemplary damages in an amount sufficient to punish Bard's conduct and deter like conduct by Bard and other similarly situated persons and entities in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. Compensatory damages, including without limitation past and future medical expenses; past and future pain and suffering; past and future emotional distress; past and future loss of enjoyment of life; past and future loss of consortium; past and future lost wages and loss of earning capacity; funeral and burial expenses; and other consequential damages as allowed by law;

B. Punitive damages in an amount sufficient to punish Defendants and deter similar conduct in the future;

C. Disgorgement of profits;

D. Restitution;

E. Statutory damages, where authorized;

F. Costs of suit;

G. Reasonable attorneys' fees, where authorized;

H. Prejudgment interest as allowed by law;

I. Post-judgment interest at the highest applicable statutory or common law rate from the date of judgment until satisfaction of judgment;

J. Any other interest recoverable under the law of any action pending in this MDL; and

K. Such other additional and further relief as Plaintiffs may be entitled to in law or in equity.

RESPECTFULLY SUBMITTED this ____ day of February, 2016.

GALLAGHER & KENNEDY, P.A.

By: */s/*
Robert W. Boatman
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Attorneys for Plaintiffs

I hereby certify that on this ____ day of February, 2016, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/

5121823/26997-1

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MDL-15-02641-PHX-DGC **CASE MANAGEMENT ORDER NO. 5** **(Plaintiff and Defendant Profile Forms)**

The parties have agreed upon the use of an abbreviated Plaintiff Profile Form ("PPF") (Exhibit 1) attached to this Order. Except as expressly noted herein, the PPF shall be completed in each currently pending case, and in all cases that become part of this MDL by virtue of being filed in, removed to, or transferred to this Court on or after the date of this Order.

Each plaintiff in currently filed cases (except as noted herein) shall submit a completed PPF to defendants within 60 days of the date of this Order. In cases that have been filed in, removed to, or transferred to this MDL on or after the date of this Order, each plaintiff shall submit a completed PPF to defendants within 60 days of filing the complaint. Each plaintiff is required to provide defendants with a PPF that is substantially complete in all respects, answering every question in the PPF, even if a plaintiff can answer the question in good faith only by indicating "not applicable" or "unknown." The PPF shall be signed by the plaintiff under penalty of perjury. If a plaintiff is suing in a representative or derivative capacity, the PPF shall be completed by the person with the legal authority to represent the estate or the person under legal disability. Plaintiff spouses with a claim for loss of consortium shall also sign the PPF, attesting that the responses made to the loss of consortium questions in the PPF

are true and correct to the best of his or her knowledge, information and belief, formed after due diligence and reasonable inquiry.

A completed PPF shall be considered interrogatory answers under Fed. R. Civ. P. 33 and responses to requests for production under Fed. R. Civ. P. 34, and will be governed by the standards applicable to written discovery under Federal Rules 26 through 37. The interrogatories and requests for production in the PPF shall be answered without objection as to the question posed in the agreed upon PPF. This section does not prohibit a plaintiff from withholding or redacting information from medical or other records provided with the PPF based upon a recognized privilege. If information is withheld or redacted on the basis of privilege, plaintiff shall provide defendants with a privilege log that complies with Fed. R. Civ. P. 26(b)(5) simultaneously with the submission of the PPF.

If a plaintiff does not submit a PPF within the time specified in this Order, defendants shall mail an overdue letter by e-mail and U.S. mail to Plaintiffs' Co-Lead Counsel and the plaintiffs' individual representative counsel, stating that defendants may move to dismiss that plaintiff's case within 20 days of receipt of the letter. If no PPF is received within those 20 additional days, defendants may move immediately to dismiss that plaintiff's case. If defendants receive a PPF that is not substantially complete, defendants' counsel shall send a deficiency letter within 14 days of receipt of a PPF, as applicable by e-mail and U.S. mail to Plaintiffs' Co-Lead Counsel and the plaintiffs' individual representative counsel, identifying the purported deficiencies. Plaintiff shall have 20 days from receipt of that letter to serve a PPF that is substantially complete in all respects. This letter shall include sufficient detail for the parties to meet and confer regarding the alleged deficiencies.

Within 45 days of receipt of a substantially complete PPF for an individual plaintiff, the defendants shall provide the plaintiff with a completed Defendants' Profile Form (Exhibit 2) attached to this order.

The procedures outlined in this Order shall not apply to the following cases:

/ / /

/ / /

Plaintiff	Original Jurisdiction
1. Cason, Pamela	GA – N.D. Ga. 1:12-cv-1288
2. Coker, Jennifer	GA – N.D. Ga. 1:13-cv-515
3. Conn, Charles	TX – S.D. Tex. 4:14-cv-298
4. Ebert, Melissa	PA – E.D. Pa. 5:12-cv-1253
5. Fox, Susan	TX – N.D. Tex. 3:14-cv-133
6. Henley, Angela	WI – E.D. Wis. 2:14-cv-59
7. Keen, Harry	PA – E.D. Pa. 5:13-cv-5361
8. Milton, Gary	GA – M.D. Ga. 5:14-cv-351
9. Mintz, Jessica	NY – E.D.N.Y. 2:14-v-4942
10. Ocasio, Denise	FL – M.D. Fla. 8:13-cv-1962
11. Rivera (McClarty), Vicki	MI – E.D. Mich. 4:14-cv-13627
12. Smith, Erin	TX – E.D. Tex. 1:13-cv-633
13. Tillman, Lessie	FL – M.D. Fla. 3:13-cv-222

The parties are relieved from preparing or exchanging profile forms in those particular cases.

On or before January 15, 2016, the parties shall submit proposed Plaintiffs' and Defendants' Fact Sheets for the Court's consideration. These forms will provide the parties with more detailed information about each plaintiff and his or her case. Those forms will be completed and exchanged only in cases designated for further discovery or for consideration as a bellwether case. The court will issue a subsequent Order outlining the procedures applicable to those more detailed forms.

Dated this 17th day of December, 2015.

David G. Campbell
United States District Judge

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

MDL No. 2641
In Re Bard IVC Filter Products Liability Litigation

In completing this **Plaintiff Profile Form**, you are under oath and must provide information that is true and correct to the best of your knowledge. The Plaintiff Profile Form shall be completed in accordance with the requirements set forth in the applicable Case Management Order.

1. CASE INFORMATION

Caption: _____ **Date:** _____

Docket No.: _____

Plaintiff's attorney and Contact information:

_____

_____

_____

2. PLAINTIFF INFORMATION

Name: _____

Maiden Name: _____

Address: _____

Date of birth: _____

Social Security No.: _____

Occupation: _____

Spouse: _____

Is Spouse Making Claim for Loss of Consortium? ☐Yes ☐ No

3. DEVICE INFORMATION

A. **Filter Model (e.g., Recovery®, G2®, etc.):** _____
B. **Lot Number:** _____
C. **Date of Bard IVC Filter implant:** _____
D. **Attach medical evidence of product identification and operative report for filter placement.**

E. Please check all the reasons why you believe your Bard Filter was placed:

☐ Filter Placed After Being Diagnosed with Deep Vein Thrombosis/Pulmonary Embolism

☐ Filter Placed in Conjunction with or before Orthopedic Procedure

☐ Filter Placed in Conjunction with Trauma Situation/Motor vehicle accident

☐ Filter Placed in Conjunction with or before Bariatric Procedure

☐ Other Reason(s) for implant (explain): _____

_____

☐ Unknown

☐ See medical records attached

F. Provide the name and address of both the doctor who implanted the Bard Filter and the hospital or medical facility at which the filter was placed:

Doctor:_____

_____

Hospital/MedicalFacility:_____

_____

4. FAILURE MODE ALLEGED

Please check all failure mode(s) that you allege apply to your Bard Filter:

☐ Fracture

☐ Perforation of filter strut(s) into organs

☐ Migration of entire filter to heart

☐ Tilt with filter embedded in wall of the IVC

☐ Device unable to be retrieved

☐ Bleeding

☐ Other failure mode(s)

If other, please describe _____

_____

5. REMOVAL INFORMATION

A. Has your Bard Filter been removed?

☐Yes

☐ No

☐ Unknown

B. If your Bard Filter has been removed or a doctor has attempted to remove your Filter, please check all that apply regarding the removal or attempted removal procedure(s):

☐Removed percutaneously

☐ Removed via an open abdominal procedure

☐ Removed via an open chest procedure

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Unknown

☐ See medical records attached

C. Provide the name(s) and address(es) of both the doctor(s) who removed your Bard Filter (or attempted to remove it) and the hospital or medical facility where removal/attempted removal occurred:

Filter Removal/Attempted Removal #1

Doctor:_____

Hospital/MedicalFacility:_____

Filter Removal/Attempted Removal #2

Doctor:_____

Hospital/MedicalFacility:_____

6. FRACTURED STRUTS

A. Do you claim that your Bard Filter fractured?

☐ Yes

☐ No

If you answered YES, answer the below questions in this section.

If you answered NO, skip the rest of Section 6 and go below to section 7 - "Outcome Attributed to Device."

B. Are any fractured filter struts retained in your body?

☐ Yes

☐ No

☐ Unknown

If yes, identify the location(s) within your body of each retained filter strut.

_____

_____

C. Have any fractured filter struts been removed from your body?

☐ Yes

☐ No

☐ Unknown

D. If any fractured filter <u>strut</u> has been removed (or a doctor has attempted to remove any strut), please check <u>all</u> that apply regarding the removal / attempted removal procedure(s):

☐ Removed percutaneously

☐ Removed via an open abdominal procedure

☐ Removed via an open chest procedure

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe_____

☐ Unknown

E. Provide the name and address of both the doctor who removed (or attempted to remove) the <u>filter strut(s)</u> and the hospital or medical facility at which it was removed (or attempted to be removed)

Filter <u>Strut</u> Removal/Attempted Removal #1

Doctor:_____

Hospital/MedicalFacility:_____

Filter Strut Removal/Attempted Removal #2

Doctor:_____

Hospital/MedicalFacility:_____

7. OUTCOME ATTRIBUTED TO DEVICE

A. Do you claim to be suffering from any bodily injuries, including psychological injuries that are above and beyond usual pain and suffering and mental anguish, related to the Filter?

☐ Yes

☐ No

If your answer is "**Yes**," please list all symptoms and injuries you claim to have suffered :

_____

_____

Of the injuries/symptoms you listed above, which do you claim to be suffering from at the current time:

_____

_____

***

Plaintiff reserves the right to supplement any and all responses upon the receipt of additional information.

_____ _____

Date Signature of Plaintiff

_____ _____

Date Signature of Plaintiff – Spouse (signature only necessary if Loss of Consortium is alleged)

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION

MDL No. 2641

DEFENDANT BARD CASE PROFILE FORM

For each case, the Bard Defendants must complete this Defendant Profile Form ("DPF") in accordance with the schedule established by the Court's Pretrial Order. In completing this Profile Form, you must answer every question.

I. CASE INFORMATION

This defendant profile form pertains to the following case:

Case caption: _____

Civil Action No.: _____

Court in which action was originally filed: _____

II. CONTACTS WITH IMPLANTING AND REMOVING PHYSICIANS

Plaintiff has identified each healthcare provider who implanted, removed and/or attempted to remove Bard's Filter. With respect to each of those healthcare providers, provide the following information:

A. CONSULTATION AGREEMENT

1. As to the identified healthcare providers, state whether Bard has consulting agreement with the healthcare provider relating to IVC filters that Bard has been able to locate after a reasonable and diligent search.

_____

_____

B. SALES REPRESENTATIVE AND OTHER RELATED CONTACTS

As to each sales representative, territory manager and district manager who had any contact with an identified physician or healthcare provider, set forth the following:

1. Identity and last known address and telephone number of Representative(s):

_____

_____

As to the individual who Bard believes was the territory manager and district manger for the territory where the filter was implanted at the time of implant, set forth the following:

2. Identify the name of the territory manager and district manger, the dates of employment for each, and, if no longer employed by Bard, provide the last known address:

Territory Manager:

Name: _____

Employment Dates: _____

If former, last known address: _____

District Manager:

Name: _____

Employment Dates: _____

If former, last known address: _____

III. MANUFACTURING INFORMATION

A. Identify the lot number(s) for the Bard filter implanted in Plaintiff: _____

B. Identify the lot number for the Bard device used to remove or used to attempt to remove the Bard Filter implanted into Plaintiff:

_____

C. Identify the location and date of manufacture for each lot set forth in response to A and B above: _____

IV. DOCUMENTS

A. Please produce the following:

1. The Device History Record (DHR) for the Bard filter at issue, or, if already produced, provide the bates number for the DHR.

2. The Bard complaint file relating to plaintiff's claims, or, in the alternative if already produced, provide the bates number for the complaint.

3. The bates numbers for any documents previously produced that reference the implanting physician and/or the hospital or facility where the device as placed, that Bard is able to identify after a reasonable and diligent search.

4. Any consulting agreement relating to IVC filters that Bard has entered with the physician that implanted the filter.

5. With regard to the plaintiff, any Med Watch Adverse Event Reports in Bard's possession.

_____

Attorney for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

_____

[Signature]

James R. Condo (#005867)
Amanda Sheridan (#005867)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
JCondo@swlaw.com
ASheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
Richard.North@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

MDL NO. 15-02641-PHX-DGC

DEFENDANTS C. R. BARD, INC.'S AND BARD PERIPHERAL VASCULAR, INC.'S ANSWER TO PLAINTIFFS' MASTER COMPLAINT; JURY TRIAL DEMAND

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV") (Bard and BPV are collectively "Defendants") hereby answer the Plaintiffs' Master Complaint for Damages for Individual Claims ("Complaint" or "Plaintiffs' Complaint"). Defendants hereby deny any and all Causes of Action or factual allegations added by any individual plaintiff through use of the Short Form Complaint for Damages. Defendants reserve the right to seek dismissal of any case adopting the Complaint that is inconsistent

with the terms of any pretrial or case management order entered by the Court in this matter, or for any other reason.

Defendants deny all allegations set forth in the Master Complaint except to the extent such allegations are specifically admitted below.

RESPONSE TO SPECIFIC ALLEGATIONS

1. Defendants admit that Plaintiffs purport to bring this action as stated in the Complaint, but Defendants deny that there is any legal or factual basis for such relief. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters. Defendants deny the remaining allegations contained in Paragraph 1 of Plaintiffs' Complaint.

2. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali® (hereinafter "Bard Inferior Vena Cava Filters"). Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. No response is required with respect to the statement contained in Paragraph 2 of Plaintiffs' Complaint pertaining to the Recovery® Cone. To the extent a response is required, Defendants deny the propriety of Plaintiffs' reference to the Recovery® Cone Removal System as a "Bard IVC Filter," as suggested in Paragraph 2 of Plaintiffs' Complaint.[1]

[1] Defendants further deny the propriety of the use, reference, or incorporation, express or implied, of the term "Bard IVC Filter" to include the Recovery® Cone Removal System throughout Plaintiffs' Complaint. Defendants expressly deny that the Recovery® Cone Removal System is an inferior vena cava filter and deny that any plaintiff alleges injury indirectly or directly related to the Recovery® Cone Removal System. Defendants expressly incorporate their denial to the allegation that the Recovery® Cone Removal System may be properly designated as an inferior vena cava filter in response to every allegation in Plaintiffs' Complaint wherein the term "Bard IVC Filters" is included. To aid in clarity, Defendants will utilize the term "Bard Inferior Vena Cava Filters"

3. Defendants admit that Plaintiffs purport to bring their actions for damages related to Bard's manufacture or BPV's design, sale, marketing, and/or distribution of Recovery®, G2®, G2®X, Eclipse®, Meridian®, or Denali® filters. Defendants deny the remaining allegations contained in Paragraph 3 of Plaintiffs' Complaint.

4. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of Plaintiffs' Complaint regarding the condition of Bard Inferior Vena Cava Filters upon receipt by any physician and, on that basis, deny the allegations. Defendants deny the remaining allegations contained in Paragraph 4 of Plaintiffs' Complaint.

5. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5 of Plaintiffs' Complaint regarding the manner in which plaintiffs' physicians used Bard Inferior Vena Cava Filters and, on that basis, deny the allegations. Defendants deny the remaining allegations contained in Paragraph 5 of Plaintiffs' Complaint.

6. The allegations contained in Paragraph 6 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny that there is any defect in any Bard Inferior Vena Cava Filter. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 6 of Plaintiffs' Complaint.

---

throughout this Answer, as defined in response to Paragraph 2 of Plaintiffs' Complaint, *supra.*

7. The allegations contained in Paragraph 7 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny that there is any defect in any Bard Inferior Vena Cava Filter. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 7 of Plaintiffs' Complaint.

PARTIES

8. The allegations of Paragraph 8 of Plaintiffs' Complaint are not directed to Bard or BPV and, as a result, require no response by Defendants. However, to the extent Paragraph 8 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

9. The allegations of Paragraph 9 of Plaintiffs' Complaint are not directed to Bard or BPV and, as a result, require no response by Defendants. However, to the extent Paragraph 9 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

10. Defendants deny the allegations contained in Paragraph 10 of Plaintiffs' Complaint.

11. Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in various states and jurisdictions throughout the United States, including the State of Arizona. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®,

and Denali®. Defendants deny the remaining allegations contained in Paragraph 11 of Plaintiffs' Complaint.

12. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in various states and jurisdictions throughout the United States, including the State of Arizona. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 12 of Plaintiffs' Complaint.

13. The allegations contained in Paragraph 13 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny the allegations.

14. The allegations contained in Paragraph 14 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny the allegations.

15. The allegations contained in Paragraph 15 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny the allegations.

16. The allegations contained in Paragraph 16 of Plaintiffs' Complaint include legal conclusions, which do not require a response. To the extent a response is required, Defendants deny the allegations.

17. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names

Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 17 of Plaintiffs' Complaint.

18. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 18 of Plaintiffs' Complaint.

19. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 19 of Plaintiffs' Complaint.

JURISDICTION AND VENUE

20. The allegations contained in Paragraph 20 of Plaintiffs' Complaint are legal conclusions, which do not require a response. Defendants further state that the allegations in Plaintiffs' Complaint are insufficient on their own to establish jurisdiction under 28 U.S.C. § 1332. Plaintiffs can only establish jurisdiction under 28 U.S.C. § 1332 by pleading facts in a Short Form Complaint that show diversity of citizenship.

21. Defendants admit that BPV is an Arizona Corporation that is authorized to do business, and does business, in Arizona and in various states and jurisdictions throughout the United States. Defendants further admit that Bard is authorized to do business, and does business, in Arizona and in various states and jurisdiction throughout the United States.

22. The allegations contained in Paragraph 22 of Plaintiffs' Complaint purport to quote an order of the Judicial Panel on Multidistrict Litigation. Defendants do not deny that the order exists but further state that the order speaks for itself, and any characterization inconsistent with the order is denied.

23. The allegations contained in Paragraph 23 of Plaintiffs' Complaint purport to quote an order of the Judicial Panel on Multidistrict Litigation. Defendants do not deny that the order exists but further state that the order speaks for itself, and any characterization inconsistent with the order is denied.

24. The allegations contained in Paragraph 24 of Plaintiffs' Complaint purport to quote this Court's Case Management Order No. 2. Defendants do not deny that the order exists but further state that the order speaks for itself, and any characterization inconsistent with the order is denied.

GENERAL FACTUAL ALLEGATIONS

25. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any remaining allegations of Paragraph 25 of Plaintiffs' Complaint.

26. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that inferior vena cava filters may be designed for permanent placement, temporary placement, or both. Defendants deny any remaining allegations of Paragraph 26 of Plaintiffs' Complaint.

27. Defendants admit that the inferior vena cava is a large vein that receives blood from the lower regions of the body and delivers it to the right atrium of the heart. Defendants further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to human health, including sometimes death. Defendants deny any remaining allegations of Paragraph 27 of Plaintiffs' Complaint.

28. Defendants admit that patients at a high risk for developing deep vein thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy, including but not limited to the medications listed in Paragraph 28 of Plaintiffs' Complaint. Defendants further admit that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 28 of Plaintiffs' Complaint and, on that basis, deny them.

29. Defendants lack knowledge or information or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market. Defendants also lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when optional or retrievable filters came to be marketed or the other allegations regarding optional or retrievable filters marketed by other manufacturers. Defendants deny any remaining allegations contained in Paragraph 29 of Plaintiffs' Complaint.

30. Defendants deny the allegations contained in Paragraph 30 of Plaintiffs' Complaint.

31. Defendants deny the allegations contained in Paragraph 31 of Plaintiffs' Complaint.

32. Defendants deny the allegations contained in Paragraph 32 of Plaintiffs' Complaint, except Defendants admit that physician input and feedback was valuable in the development of Defendants' Inferior Vena Cava Filters. Defendants deny any remaining allegations contained in Paragraph 32 of Plaintiffs' Complaint.

33. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding other manufacturers' belief or motivations and, on that basis, deny them. Defendants deny any remaining allegations contained in Paragraph 33 of Plaintiffs' Complaint.

34. Defendants admit that the Recovery® Filter was cleared by the FDA for retrievable use on July 25, 2003. Defendants deny any remaining allegations contained in Paragraph 34 of Plaintiffs' Complaint.

35. Defendants deny the allegations contained in Paragraph 35 of Plaintiffs' Complaint.

36. Defendants deny the allegations contained in Paragraph 36 of Plaintiffs' Complaint.

37. To the extent the allegations contained in Paragraph 37 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants specifically deny that the known risks associated with inferior vena cava filters generally outweigh the benefits of inferior vena cava filters, which can be life-saving. Defendants deny any remaining allegations contained in Paragraph 37 of Plaintiffs' Complaint.

38. To the extent the allegations contained in Paragraph 38 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants specifically deny that the known risks associated with inferior vena cava filters generally outweigh the benefits of inferior vena cava filters, which can be life-saving. Defendants deny any remaining allegations contained in Paragraph 38 of Plaintiffs' Complaint, including all sub-parts thereof.

39. To the extent the allegations contained in Paragraph 39 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants specifically deny that the known risks associated with inferior vena cava filters generally outweigh the benefits of inferior vena cava filters, which can be life-saving. Defendants deny any remaining allegations contained in Paragraph 39 of Plaintiffs' Complaint.

40. Defendants admit that Defendants have previously and continue currently to market the Simon Nitinol Filter, which was cleared by FDA for permanent use. Defendants deny any remaining allegations contained in Paragraph 40 of Plaintiffs' Complaint.

41. Defendants admit that the Simon Nitinol Filter was initially manufactured by Nitinol Medical Technologies. Defendants further admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Recovery® Filter was developed in furtherance of those efforts. Defendants further admit that Bard acquired Nitinol Medical Technologies' inferior vena cava filter product line in 2001. Defendants deny any remaining allegations contained in Paragraph 41 of Plaintiffs' Complaint.

42. Defendants deny the allegations contained in Paragraph 42 of Plaintiffs' Complaint.

43. Defendants deny the allegations contained in Paragraph 43 of Plaintiffs' Complaint.

44. Defendants admit that the Recovery® Filter was cleared by the FDA for permanent placement on November 27, 2002, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the requirements of Section 510(k) are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations and characterizations of the FDA approval and clearance processes. Defendants deny any remaining allegations contained in Paragraph 44 of Plaintiffs' Complaint.

45. The allegations pertaining to the requirements and purpose of Section 510(k) of the Food, Drug and Cosmetic Act are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations and characterizations of the FDA approval and clearance processes. To the extent the allegations contained in Paragraph 45 of Plaintiffs' Complaint purport to quote or paraphrase the case

Horn v. Thoratec Corp., the document speaks for itself, and any characterization inconsistent with the case law is denied. Defendants deny any remaining allegations contained in Paragraph 45 of Plaintiffs' Complaint.

46. The allegations pertaining to the requirements and purpose of Section 510(k) of the Food, Drug and Cosmetic Act are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations and characterizations of the FDA approval and clearance processes. To the extent the allegations contained in Paragraph 46 of Plaintiffs' Complaint purport to quote or paraphrase the case *Medtronic v. Lohr*, the case speaks for itself, and any characterization inconsistent with the case law is denied. Defendants deny any remaining allegations contained in Paragraph 46 of Plaintiffs' Complaint.

47. The allegations pertaining to the post-market obligations of Defendants are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations and characterizations accurately and completely reflect Defendants' post-market obligations. To the extent the allegations contained in Paragraph 47 of Plaintiffs' Complaint purport to quote or paraphrase the case *Wyeth v. Levine*, the document speaks for itself, and any characterization inconsistent with the case law is denied. Defendants deny any remaining allegations contained in Paragraph 47 of Plaintiffs' Complaint.

48. Defendants admit that the Recovery® Filter was cleared by the FDA for retrievable placement on July 25, 2003, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act.

49. Defendants deny the allegations contained in Paragraph 49 of Plaintiffs' Complaint.

50. Defendants deny the allegations contained in Paragraph 50 of Plaintiffs' Complaint.

51. Defendants admit that a nickel-titanium alloy named Nitinol is used in the manufacture of the Recovery Filter. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires form two levels of filtration for emboli: the legs provide the lower level of filtration, and the arms provide the upper level of filtration. Defendants deny any remaining allegations contained in Paragraph 51 of Plaintiffs' Complaint.

52. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires form two levels of filtration for emboli: the legs provide the lower level of filtration, and the arms provide the upper level of filtration. Defendants deny any remaining allegations contained in Paragraph 52 of Plaintiffs' Complaint.

53. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. To the extent the allegations contained in Paragraph 53 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the case law is denied. Defendants deny any remaining allegations contained in Paragraph 53 of Plaintiffs' Complaint.

54. Defendants admit that Nitinol possesses shape-memory. Defendants deny any remaining allegations contained in Paragraph 54 of Plaintiffs' Complaint.

55. Defendants admit that Nitinol possesses shape-memory and that the Recovery® Filter was designed to be inserted endovascularly. Defendants further admit that the Recovery® Filter is designed to be delivered via an introducer sheath, which is included in the delivery system for the device. Defendants deny any remaining allegations of Paragraph 55 of Plaintiffs' Complaint.

56. Defendants admit that the Recovery® Filter was designed to be inserted endovascularly via an introducer sheath, which is included in the delivery system for the device. Defendants admit that the Recovery® Filter was designed to be retrieved

endovascularly as well. Defendants deny any remaining allegations of Paragraph 56 of Plaintiffs' Complaint.

57. Defendants admit that the Recovery® Filter is intended for the uses described in the Instructions for Use which accompany each device. To the extent the allegations contained in Paragraph 57 of Plaintiffs' Complaint purport to quote or paraphrase the Recovery® Filter Instructions for Use, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 57 of Plaintiffs' Complaint.

58. The allegations pertaining to FDA requirements related to the Recovery® Cone Removal System are legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations contained in Paragraph 58 of Plaintiffs' Complaint.

59. Defendants admit that the Recovery® Cone Removal System has been marketed previously as a Class I medical device and a cleared accessory of Bard's Inferior Vena Cava Filters. Defendants deny any remaining allegations contained in Paragraph 59 of Plaintiffs' Complaint.

60. Defendants deny the allegations contained in Paragraph 60 of Plaintiffs' Complaint.

61. Defendants deny the allegations contained in Paragraph 61 of Plaintiffs' Complaint.

62. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every

manufacturer of inferior vena cava filters. Defendants deny the remaining allegations contained in Paragraph 62 of Plaintiffs' Complaint.

63. Defendants deny the allegations contained in Paragraph 63 of Plaintiffs' Complaint.

64. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations contained in Paragraph 64 of Plaintiffs' Complaint.

65. The allegations pertaining to FDA's MAUDE database contain legal conclusions of law to which no answer is required. To the extent a response is required, Defendants deny the allegations contained in Paragraph 65 of Plaintiffs' Complaint.

66. Defendants deny the allegations contained in Paragraph 66 of Plaintiffs' Complaint.

67. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 67 of Plaintiffs' Complaint.

68. Defendants admit that they BPV marketed and sold the Recovery® Filter until September 2005. Defendants further admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants further

admit that the G2® Filter was cleared by the FDA in August 2005 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 68 of Plaintiffs' Complaint.

69. Defendants admit that the G2® Filter was cleared by the FDA in August 2005 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 69 of Plaintiffs' Complaint.

70. Defendants deny the allegations contained in Paragraph 70 of Plaintiffs' Complaint.

71. To the extent the allegations contained in Paragraph 71 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 71 of Plaintiffs' Complaint.

72. To the extent the allegations contained in Paragraph 72 of Plaintiffs' Complaint purport to quote or paraphrase a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 72 of Plaintiffs' Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiffs' Complaint.

74. Defendants deny the allegations contained in Paragraph 74 of Plaintiffs' Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of Plaintiffs' Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of Plaintiffs' Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of Plaintiffs' Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of Plaintiffs' Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of Plaintiffs' Complaint.

80. Defendants admit that fracture is a well-document complication that may occur with any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of filter fracture associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 80 of Plaintiffs' Complaint.

81. Defendants admit that perforation and tilt are well-document complications that may occur with any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter perforation or tilt result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of filter perforation or tilt associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 81 of Plaintiffs' Complaint.

82. Defendants admit that there are various well-documented complications that may occur as the result of the fracture, perforation, tilt, and/or migration of any inferior vena cava filter. Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 82 of Plaintiffs' Complaint, including all sub-parts thereof.

83. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 83 of Plaintiffs' Complaint, including all sub-parts thereof.

84. Defendants deny the allegations contained in Paragraph 84 of Plaintiffs' Complaint.

85. Defendants deny the allegations contained in Paragraph 85 of Plaintiffs' Complaint.

86. Defendants deny the allegations contained in Paragraph 86 of Plaintiffs' Complaint.

87. The allegations contained in Paragraph 87 of Plaintiffs' Complaint purport to quote from documents, which speak for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 87 of Plaintiffs' Complaint, including all sub-parts thereof.

88. Defendants deny the allegations contained in Paragraph 88 of Plaintiffs' Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiffs' Complaint.

90. Defendants deny the allegations contained in Paragraph 90 of Plaintiffs' Complaint.

91. Defendants deny the allegations contained in Paragraph 91 of Plaintiffs' Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiffs' Complaint.

93. Defendants deny the allegations contained in Paragraph 93 of Plaintiffs' Complaint.

94. Defendants deny the allegations contained in Paragraph 94 of Plaintiffs' Complaint.

95. The allegations contained in Paragraph 95 of Plaintiffs' Complaint purport to quote from documents, which speak for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 95 of Plaintiffs' Complaint, including all sub-parts thereof.

96. The allegations contained in Paragraph 96 of Plaintiffs' Complaint purport to quote from documents, which speak for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 96 of Plaintiffs' Complaint, including all sub-parts thereof.

97. Defendants deny the allegations contained in Paragraph 97 of Plaintiffs' Complaint.

98. Defendants admit that the Eclipse® filter, cleared by FDA in 2010, was electropolished. Defendants deny the remaining allegations contained in Paragraph 98 of Plaintiffs' Complaint.

99. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Meridian® Filter, which has caudal anchors on the six filter "arms," was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 99 of Plaintiffs' Complaint.

100. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are

continually striving to improve the life-saving performance of those devices. The Denali® Filter, which has penetration limiters on the six filter "legs," was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 100 of Plaintiffs' Complaint.

101. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Denali® Filter, which has penetration limiters on the six filter "legs," was developed in furtherance of those efforts. Defendants deny that there exists any analysis or study that definitively demonstrates that filter tilt results in a clinically significant occurrence of filter perforation. Defendants deny any remaining allegations contained in Paragraph 101 of Plaintiffs' Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiffs' Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiffs' Complaint.

104. The allegations contained in Paragraph 104 of Plaintiffs' Complaint purport to quote from the Recovery® Filter Instructions for Use, which speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 104.

105. The allegations contained in Paragraph 105 of Plaintiffs' Complaint purport to quote from the Recovery® Filter Instructions for Use, which speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 105.

106. Defendants deny the allegations contained in Paragraph 106 of Plaintiffs' Complaint.

107. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, they are continually evaluating the performance of such devices. To that end, a multifunctional team evaluated occurrences of adverse events related to the Recovery® Filter in 2004. Defendants deny any remaining allegations contained in Paragraph 107 of Plaintiffs' Complaint.

108. The allegations contained in Paragraph 108 of Plaintiffs' Complaint purport to quote from a document, which speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 108.

109. The allegations contained in Paragraph 109 of Plaintiffs' Complaint purport to quote from a document, which speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 109.

110. Defendants deny the allegations contained in Paragraph 110 of Plaintiffs' Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of Plaintiffs' Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of Plaintiffs' Complaint.

113. Defendants admit that the G2® Filter was cleared by the FDA in August 2005 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. To the extent the allegations contained in Paragraph 113 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 113 of Plaintiffs' Complaint.

114. To the extent the allegations contained in Paragraph 114 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 114 of Plaintiffs' Complaint.

115. To the extent the allegations contained in Paragraph 115 of Plaintiffs' Complaint purport to quo te or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 115 of Plaintiffs' Complaint.

116. To the extent the allegations contained in Paragraph 116 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 116 of Plaintiffs' Complaint.

117. To the extent the allegations contained in Paragraph 117 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 117 of Plaintiffs' Complaint.

118. Defendants admit the G2® Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter. To the extent the allegations contained in Paragraph 118 of Plaintiffs' Complaint purport to quote or paraphrase from documents, the documents speak for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 118 of Plaintiffs' Complaint.

119. Defendants admit that the G2® Filter System was marketed after clearance was obtained by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny the remaining allegations contained in Paragraph 119 of Plaintiffs' Complaint.

120. Defendants admit that the G2® Filter System and Simon Nitinol Filter were both available for purchase beginning in 2005. Defendants deny the remaining allegations contained in Paragraph 120 of Plaintiffs' Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of Plaintiffs' Complaint.

122. Defendants deny the allegations contained in Paragraph 122 of Plaintiffs' Complaint.

123. Defendants deny the allegations contained in Paragraph 123 of Plaintiffs' Complaint.

124. Defendants deny the allegations contained in Paragraph 124 of Plaintiffs' Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiffs' Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiffs' Complaint.

127. Defendants deny the allegations contained in Paragraph 127 of Plaintiffs' Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of Plaintiffs' Complaint.

129. Defendants deny the allegations contained in Paragraph 129 of Plaintiffs' Complaint.

130. Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, tilt and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture, perforation, tilt, and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Bard states that there are incidents related to the occurrence of known complications associated with every manufacturer of

inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 130 of Plaintiffs' Complaint, including all sub-parts thereof.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiffs' Complaint. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiffs' Complaint.

133. Defendants deny the allegations contained in Paragraph 133 of Plaintiffs' Complaint. By way of further response, Bard states that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications.

134. To the extent the allegations contained in Paragraph 134 of Plaintiffs' Complaint purport to quote or paraphrase from a document, the document speaks for itself, and any characterization inconsistent with the document is denied. Defendants deny any remaining allegations contained in Paragraph 134 of Plaintiffs' Complaint.

135. Defendants deny the allegations contained in Paragraph 135 of Plaintiffs' Complaint.

136. Defendants admit the G2® Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants admit that the G2® Filter was originally cleared by the FDA for permanent use. Defendants further admit that the G2® Filter was subsequently cleared by the FDA for optional use as a retrievable inferior vena cava filter. Defendants further admit that the G2® Express filter and G2® Filter are similarly designed, except that the G2® Express Filter was equipped with a snarable "hook" to facilitate retrieval via a snare device. Defendants deny any remaining allegations contained in Paragraph 136 of Plaintiffs' Complaint.

137. Defendants deny the allegations contained in Paragraph 137 of Plaintiffs' Complaint.

138. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Eclipse® Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 138 of Plaintiffs' Complaint.

139. Defendants admit that the Eclipse® filter, cleared by FDA in 2010, was electropolished. Defendants deny the remaining allegations contained in Paragraph 139 of Plaintiffs' Complaint.

140. To the extent the allegations contained in Paragraph 140 of Plaintiffs' Complaint purport to quote or paraphrase from documents, the documents speaks for themselves, and any characterization inconsistent with the documents is denied. Defendants deny any remaining allegations contained in Paragraph 140 of Plaintiffs' Complaint.

141. Defendants deny the allegations contained in Paragraph 141 of Plaintiffs' Complaint.

142. Defendants deny the allegations contained in Paragraph 142 of Plaintiffs' Complaint.

143. Defendants deny the allegations contained in Paragraph 143 of Plaintiffs' Complaint.

144. Defendants admit that the Meridian® Filter was cleared by the United States Food and Drug Administration in 2011 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 144 of Plaintiffs' Complaint.

145. To the extent the allegations contained in Paragraph 145 of Plaintiffs' Complaint purport to quote or paraphrase from documents, the documents speak for themselves, and any characterization inconsistent with the documents is denied. The

allegations pertaining to the requirements of Section 510(k) are legal conclusions of law to which no answer is required. Defendants deny any remaining allegations contained in Paragraph 145 of Plaintiffs' Complaint.

146. Defendants deny the allegations contained in Paragraph 146 of Plaintiffs' Complaint.

147. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Meridian® Filter was developed in furtherance of those efforts. Defendants admit that the Meridian® Filter is made of nitinol. Defendants deny any remaining allegations contained in Paragraph 147 of Plaintiffs' Complaint.

148. Defendants admit that the Meridian® Filter is electropolished and that the Meridian® Filter has caudal anchors on the six filter "arms". Defendants deny any remaining allegations contained in Paragraph 148 of Plaintiffs' Complaint.

149. Defendants deny the allegations contained in Paragraph 149 of Plaintiffs' Complaint.

150. Defendants deny the allegations contained in Paragraph 150 of Plaintiffs' Complaint.

151. Defendants admit that the Denali® Filter was cleared by the United States Food and Drug Administration in 2013 pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 151 of Plaintiffs' Complaint.

152. To the extent the allegations contained in Paragraph 152 of Plaintiffs' Complaint purport to quote or paraphrase from documents, the documents speak for themselves, and any characterization inconsistent with the documents is denied. The allegations pertaining to the requirements of Section 510(k) are legal conclusions of law to

which no answer is required. Defendants deny any remaining allegations contained in Paragraph 152 of Plaintiffs' Complaint.

153. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Meridian® Filter was developed in furtherance of those efforts. Defendants admit that the Meridian® Filter is made of nitinol. Defendants admit that the Meridian® Filter is electropolished and that the Meridian® Filter has caudal anchors, cranial anchors, and penetration limiters. Defendants deny any remaining allegations contained in Paragraph 153 of Plaintiffs' Complaint.

154. Defendants deny the allegations contained in Paragraph 154 of Plaintiffs' Complaint.

155. Defendants deny the allegations contained in Paragraph 155 of Plaintiffs' Complaint.

156. Defendants deny the allegations contained in Paragraph 156 of Plaintiffs' Complaint.

157. Defendants deny the allegations contained in Paragraph 157 of Plaintiffs' Complaint.

158. Defendants deny the allegations contained in Paragraph 158 of Plaintiffs' Complaint.

159. Defendants deny the allegations contained in Paragraph 159 of Plaintiffs' Complaint.

160. Defendants incorporate by reference their responses to Paragraphs 1-159 of Plaintiffs' Complaint as if fully set forth herein.

161. Defendants deny the allegations contained in Paragraph 161 of Plaintiffs' Complaint.

162. Defendants deny the allegations contained in Paragraph 162 of Plaintiffs' Complaint.

163. Defendants deny the allegations contained in Paragraph 163 of Plaintiffs' Complaint.

164. Defendants deny the allegations contained in Paragraph 164 of Plaintiffs' Complaint.

165. The allegations contained in Paragraph 165 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 165 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

COUNT I: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

166. Defendants incorporate by reference their responses to Paragraphs 1-165 of Plaintiffs' Complaint as if fully set forth herein.

167. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding the brand of any inferior vena cava filter implanted in any plaintiff and, on that basis, denies the allegations.

168. Defendants deny the allegations contained in Paragraph 168 of Plaintiffs' Complaint.

169. Defendants deny the allegations contained in Paragraph 169 of Plaintiffs' Complaint.

170. Defendants deny the allegations contained in Paragraph 170 of Plaintiffs' Complaint.

COUNT II: STRICT PRODUCTS LIABILITY – INFORMATION DEFECT

171. Defendants incorporate by reference their responses to Paragraphs 1-170 of Plaintiffs' Complaint as if fully set forth herein.

172. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding the brand of any inferior vena cava filter implanted in any

plaintiff and, on that basis, deny the allegations. Defendants deny any remaining allegations contained in Paragraph 172 of Plaintiffs' Complaint.

173. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali® (hereinafter "Bard Inferior Vena Cava Filters"). Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 173 of Plaintiffs' Complaint.

174. Defendants deny the allegations contained in Paragraph 174 of Plaintiffs' Complaint.

175. Defendants deny the allegations contained in Paragraph 175 of Plaintiffs' Complaint, including all sub-parts thereof.

176. Defendants deny the allegations contained in Paragraph 176 of Plaintiffs' Complaint.

177. Defendants deny the allegations contained in Paragraph 177 of Plaintiffs' Complaint.

178. Defendants deny the allegations contained in Paragraph 178 of Plaintiffs' Complaint.

179. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 179 of Plaintiffs' Complaint and, on that basis, deny the allegations.

180. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 180 of Plaintiffs' Complaint and, on that basis, deny the allegations.

181. Defendants deny the allegations contained in Paragraph 181 of Plaintiffs' Complaint.

COUNT III: STRICT PRODUCTS LIABILITY – DESIGN DEFECT

182. Defendants incorporate by reference their responses to Paragraphs 1-181 of Plaintiffs' Complaint as if fully set forth herein.

183. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali® (hereinafter "Bard Inferior Vena Cava Filters"). Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 183 of Plaintiffs' Complaint.

184. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 184 of Plaintiffs' Complaint and, on that basis, deny the allegations.

185. Defendants deny the allegations contained in Paragraph 185 of Plaintiffs' Complaint.

186. Defendants deny the allegations contained in Paragraph 186 of Plaintiffs' Complaint.

187. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 187 of Plaintiffs' Complaint and, on that basis, deny the allegations.

188. Defendants deny the allegations contained in Paragraph 188 of Plaintiffs' Complaint.

189. Defendants deny the allegations contained in Paragraph 189 of Plaintiffs' Complaint.

190. Defendants deny the allegations contained in Paragraph 190 of Plaintiffs' Complaint.

191. Defendants deny the allegations contained in Paragraph 191 of Plaintiffs' Complaint.

COUNT IV: NEGLIGENCE – DESIGN

192. Defendants incorporate by reference their responses to Paragraphs 1-191 of Plaintiffs' Complaint as if fully set forth herein.

193. Defendants deny the allegations contained in Paragraph 193 of Plaintiffs' Complaint, including all sub-parts thereof.

194. Defendants deny the allegations contained in Paragraph 194 of Plaintiffs' Complaint, including all sub-parts thereof.

195. The allegations contained in Paragraph 195 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 195 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

196. Defendants deny the allegations contained in Paragraph 196 of Plaintiffs' Complaint, including all sub-parts thereof.

197. Defendants deny the allegations contained in Paragraph 197 of Plaintiffs' Complaint.

COUNT V: NEGLIGENCE – MANUFACTURE

198. Defendants incorporate by reference their responses to Paragraphs 1-197 of Plaintiffs' Complaint as if fully set forth herein.

199. The allegations contained in Paragraph 199 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 199 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

200. Defendants deny the allegations contained in Paragraph 200 of Plaintiffs' Complaint, including all sub-parts thereof.

201. Defendants deny the allegations contained in Paragraph 201 of Plaintiffs' Complaint.

COUNT VI: NEGLIGENCE – FAILURE TO RECALL/RETROFIT

202. Defendants incorporate by reference their responses to Paragraphs 1-201 of Plaintiffs' Complaint as if fully set forth herein.

203. Defendants deny the allegations contained in Paragraph 203 of Plaintiffs' Complaint.

204. Defendants deny the allegations contained in Paragraph 204 of Plaintiffs' Complaint.

205. Defendants deny the allegations contained in Paragraph 205 of Plaintiffs' Complaint.

206. Defendants deny the allegations contained in Paragraph 206 of Plaintiffs' Complaint.

207. Defendants deny the allegations contained in Paragraph 207 of Plaintiffs' Complaint.

208. Defendants deny the allegations contained in Paragraph 208 of Plaintiffs' Complaint.

209. Defendants deny the allegations contained in Paragraph 209 of Plaintiffs' Complaint.

COUNT VII: NEGLIGENCE – FAILURE TO WARN

210. Defendants incorporate by reference their responses to Paragraphs 1-209 of Plaintiffs' Complaint as if fully set forth herein.

211. Defendants deny the allegations contained in Paragraph 211 of Plaintiffs' Complaint.

212. Defendants deny the allegations contained in Paragraph 212 of Plaintiffs' Complaint.

213. Defendants deny the allegations contained in Paragraph 213 of Plaintiffs' Complaint.

214. Defendants deny the allegations contained in Paragraph 214 of Plaintiffs' Complaint.

215. The allegations contained in Paragraph 215 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 215 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

216. Defendants deny the allegations contained in Paragraph 216 of Plaintiffs' Complaint.

217. Defendants deny the allegations contained in Paragraph 217 of Plaintiffs' Complaint.

COUNT VIII: NEGLIGENT MISREPRESENTATION

218. Defendants incorporate by reference their responses to Paragraphs 1-217 of Plaintiffs' Complaint as if fully set forth herein.

219. Defendants deny the allegations contained in Paragraph 219 of Plaintiffs' Complaint.

220. Defendants deny the allegations contained in Paragraph 220 of Plaintiffs' Complaint.

221. The allegations contained in Paragraph 221 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 221 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

222. Defendants deny the allegations contained in Paragraph 222 of Plaintiffs' Complaint.

223. Defendants deny the allegations contained in Paragraph 223 of Plaintiffs' Complaint.

224. Defendants deny the allegations contained in Paragraph 224 of Plaintiffs' Complaint.

225. Defendants deny the allegations contained in Paragraph 225 of Plaintiffs' Complaint.

226. The allegations contained in Paragraph 226 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 226 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

227. Defendants deny the allegations contained in Paragraph 227 of Plaintiffs' Complaint.

228. Defendants deny the allegations contained in Paragraph 228 of Plaintiffs' Complaint.

COUNT IX: NEGLIGENCE PER SE

229. Defendants incorporate by reference their responses to Paragraphs 1-228 of Plaintiffs' Complaint as if fully set forth herein.

230. The allegations contained in Paragraph 230 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 230 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

231. Defendants deny the allegations contained in Paragraph 231 of Plaintiffs' Complaint, including all sub-parts thereof.

232. The allegations contained in Paragraph 232 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 232 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

233. Defendants deny the allegations contained in Paragraph 233 of Plaintiffs' Complaint.

234. Defendants deny the allegations contained in Paragraph 234 of Plaintiffs' Complaint.

COUNT X: BREACH OF EXPRESS WARRANTY

235. Defendants incorporate by reference their responses to Paragraphs 1-234 of Plaintiffs' Complaint as if fully set forth herein.

236. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 236 of Plaintiffs' Complaint and, on that basis, deny the allegations.

237. Defendants admit that Bard owns a facility where inferior vena cava filters are manufactured, including previously or currently manufacturing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali® (hereinafter "Bard Inferior Vena Cava Filters"). Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters, including currently or previously designing, selling, marketing or distributing filters under the trade names Recovery®, G2®, G2®X, Eclipse®, Meridian®, and Denali®. Defendants deny the remaining allegations contained in Paragraph 237 of Plaintiffs' Complaint.

238. Defendants deny the allegations contained in Paragraph 238 of Plaintiffs' Complaint.

239. Defendants deny the allegations contained in Paragraph 239 of Plaintiffs' Complaint, including all sub-parts thereof.

240. Defendants deny the allegations contained in Paragraph 240 of Plaintiffs' Complaint.

COUNT XI: BREACH OF IMPLIED WARRANTY

241. Defendants incorporate by reference their responses to Paragraphs 1-240 of Plaintiffs' Complaint as if fully set forth herein.

242. Defendants deny the allegations contained in Paragraph 242 of Plaintiffs' Complaint.

243. Defendants deny the allegations contained in Paragraph 243 of Plaintiffs' Complaint, including all sub-parts thereof.

244. Defendants deny the allegations contained in Paragraph 244 of Plaintiffs' Complaint.

COUNT XII: FRAUDULENT MISREPRESENTATION

245. Defendants incorporate by reference their responses to Paragraphs 1-244 of Plaintiffs' Complaint as if fully set forth herein.

246. Defendants deny the allegations contained in Paragraph 246 of Plaintiffs' Complaint, including all sub-parts thereof.

247. Defendants deny the allegations contained in Paragraph 247 of Plaintiffs' Complaint.

248. Defendants deny the allegations contained in Paragraph 248 of Plaintiffs' Complaint.

249. Defendants deny the allegations contained in Paragraph 249 of Plaintiffs' Complaint.

250. Defendants deny the allegations contained in Paragraph 250 of Plaintiffs' Complaint.

251. Defendants deny the allegations contained in Paragraph 251 of Plaintiffs' Complaint.

252. Defendants deny the allegations contained in Paragraph 252 of Plaintiffs' Complaint.

253. Defendants deny the allegations contained in Paragraph 253 of Plaintiffs' Complaint.

254. Defendants deny the allegations contained in Paragraph 254 of Plaintiffs' Complaint.

255. Defendants deny the allegations contained in Paragraph 255 of Plaintiffs' Complaint.

256. Defendants deny the allegations contained in Paragraph 256 of Plaintiffs' Complaint.

257. Defendants deny the allegations contained in Paragraph 257 of Plaintiffs' Complaint.

258. Defendants deny the allegations contained in Paragraph 258 of Plaintiffs' Complaint.

259. Defendants deny the allegations contained in Paragraph 259 of Plaintiffs' Complaint.

COUNT XIII: FRAUDULENT CONCEALMENT

260. Defendants incorporate by reference their responses to Paragraphs 1-259 of Plaintiffs' Complaint as if fully set forth herein.

261. Defendants deny the allegations contained in Paragraph 261 of Plaintiffs' Complaint.

262. Defendants deny the allegations contained in Paragraph 262 of Plaintiffs' Complaint, including all sub-parts thereof.

263. Defendants deny the allegations contained in Paragraph 263 of Plaintiffs' Complaint.

264. Defendants deny the allegations contained in Paragraph 264 of Plaintiffs' Complaint.

265. Defendants deny the allegations contained in Paragraph 265 of Plaintiffs' Complaint.

266. Defendants deny the allegations contained in Paragraph 266 of Plaintiffs' Complaint.

COUNT XIV: VIOLATIONS OF APPLICABLE STATE LAW PROHIBITING CONSUMER FRAUD AND UNFAIR DECEPTIVE TRADE PRACTICES

267. Defendants incorporate by reference their responses to Paragraphs 1-266 of Plaintiffs' Complaint as if fully set forth herein.

268. The allegations contained in Paragraph 268 regarding Defendants' duty are conclusions of law, and no answer is required. To the extent a response is required, Defendants deny that the allegations contained in Paragraph 268 of Plaintiffs' Complaint fully and accurately characterize the obligations of manufacturers under applicable law.

269. Defendants deny the allegations contained in Paragraph 269 of Plaintiffs' Complaint.

270. Defendants deny the allegations contained in Paragraph 270 of Plaintiffs' Complaint.

271. Defendants deny the allegations contained in Paragraph 271 of Plaintiffs' Complaint.

272. Defendants deny the allegations contained in Paragraph 272 of Plaintiffs' Complaint.

273. Defendants deny the allegations contained in Paragraph 273 of Plaintiffs' Complaint.

274. Defendants deny the allegations contained in Paragraph 274 of Plaintiffs' Complaint.

275. Defendants deny the allegations contained in Paragraph 275 of Plaintiffs' Complaint.

276. Defendants deny the allegations contained in Paragraph 276 of Plaintiffs' Complaint.

277. Defendants deny the allegations contained in Paragraph 277 of Plaintiffs' Complaint.

278. Defendants deny the allegations contained in Paragraph 278 of Plaintiffs' Complaint.

279. Defendants deny the allegations contained in Paragraph 279 of Plaintiffs' Complaint.

280. Defendants deny the allegations contained in Paragraph 280 of Plaintiffs' Complaint.

281. Defendants deny the allegations contained in Paragraph 281 of Plaintiffs' Complaint.

282. Defendants deny the allegations contained in Paragraph 282 of Plaintiffs' Complaint.

283. Defendants deny the allegations contained in Paragraph 283 of Plaintiffs' Complaint.

284. Defendants deny the allegations contained in Paragraph 284 of Plaintiffs' Complaint.

285. Defendants deny the allegations contained in Paragraph 285 of Plaintiffs' Complaint.

286. Defendants deny the allegations contained in Paragraph 286 of Plaintiffs' Complaint.

287. Defendants deny the allegations contained in Paragraph 287 of Plaintiffs' Complaint.

288. Defendants deny the allegations contained in Paragraph 288 of Plaintiffs' Complaint.

289. Defendants deny the allegations contained in Paragraph 289 of Plaintiffs' Complaint.

290. Defendants deny the allegations contained in Paragraph 290 of Plaintiffs' Complaint.

291. Defendants deny the allegations contained in Paragraph 291 of Plaintiffs' Complaint.

292. Defendants deny the allegations contained in Paragraph 292 of Plaintiffs' Complaint.

293. Defendants deny the allegations contained in Paragraph 293 of Plaintiffs' Complaint.

294. Defendants deny the allegations contained in Paragraph 294 of Plaintiffs' Complaint.

295. Defendants deny the allegations contained in Paragraph 295 of Plaintiffs' Complaint.

296. Defendants deny the allegations contained in Paragraph 296 of Plaintiffs' Complaint.

297. Defendants deny the allegations contained in Paragraph 297 of Plaintiffs' Complaint.

298. Defendants deny the allegations contained in Paragraph 298 of Plaintiffs' Complaint.

299. Defendants deny the allegations contained in Paragraph 299 of Plaintiffs' Complaint.

300. Defendants deny the allegations contained in Paragraph 300 of Plaintiffs' Complaint.

301. Defendants deny the allegations contained in Paragraph 301 of Plaintiffs' Complaint.

302. Defendants deny the allegations contained in Paragraph 302 of Plaintiffs' Complaint.

303. Defendants deny the allegations contained in Paragraph 303 of Plaintiffs' Complaint.

304. Defendants deny the allegations contained in Paragraph 304 of Plaintiffs' Complaint.

305. Defendants deny the allegations contained in Paragraph 305 of Plaintiffs' Complaint.

306. Defendants deny the allegations contained in Paragraph 306 of Plaintiffs' Complaint.

307. Defendants deny the allegations contained in Paragraph 307 of Plaintiffs' Complaint.

308. Defendants deny the allegations contained in Paragraph 308 of Plaintiffs' Complaint.

309. Defendants deny the allegations contained in Paragraph 309 of Plaintiffs' Complaint.

310. Defendants deny the allegations contained in Paragraph 310 of Plaintiffs' Complaint.

311. Defendants deny the allegations contained in Paragraph 311 of Plaintiffs' Complaint.

312. Defendants deny the allegations contained in Paragraph 312 of Plaintiffs' Complaint.

313. Defendants deny the allegations contained in Paragraph 313 of Plaintiffs' Complaint.

314. Defendants deny the allegations contained in Paragraph 314 of Plaintiffs' Complaint.

315. Defendants deny the allegations contained in Paragraph 315 of Plaintiffs' Complaint.

316. Defendants deny the allegations contained in Paragraph 316 of Plaintiffs' Complaint.

317. Defendants deny the allegations contained in Paragraph 317 of Plaintiffs' Complaint.

318. Defendants deny the allegations contained in Paragraph 318 of Plaintiffs' Complaint.

319. Defendants deny the allegations contained in Paragraph 319 of Plaintiffs' Complaint.

320. Defendants deny the allegations contained in Paragraph 320 of Plaintiffs' Complaint.

321. Defendants deny the allegations contained in Paragraph 321 of Plaintiffs' Complaint.

322. Defendants deny the allegations contained in Paragraph 322 of Plaintiffs' Complaint.

323. Defendants deny the allegations contained in Paragraph 323 of Plaintiffs' Complaint.

COUNT XV: LOSS OF CONSORTIUM

324. Defendants incorporate by reference their responses to Paragraphs 1-323 of Plaintiffs' Complaint as if fully set forth herein.

325. Defendants deny the allegations contained in Paragraph 325 of Plaintiffs' Complaint.

326. Defendants deny the allegations contained in Paragraph 326 of Plaintiffs' Complaint.

327. Defendants deny the allegations contained in Paragraph 327 of Plaintiffs' Complaint.

328. Defendants deny the allegations contained in Paragraph 328 of Plaintiffs' Complaint.

329. Defendants deny the allegations contained in Paragraph 329 of Plaintiffs' Complaint.

330. Defendants deny the allegations contained in Paragraph 330 of Plaintiffs' Complaint.

COUNT XVI: WRONGFUL DEATH

331. Defendants incorporate by reference their responses to Paragraphs 1-330 of Plaintiffs' Complaint as if fully set forth herein.

332. Defendants deny the allegations contained in Paragraph 332 of Plaintiffs' Complaint.

333. Defendants deny the allegations contained in Paragraph 333 of Plaintiffs' Complaint.

334. Defendants deny the allegations contained in Paragraph 334 of Plaintiffs' Complaint.

335. Defendants deny the allegations contained in Paragraph 335 of Plaintiffs' Complaint.

COUNT XVII: SURVIVAL

336. Defendants incorporate by reference their responses to Paragraphs 1-335 of Plaintiffs' Complaint as if fully set forth herein.

337. Defendants deny the allegations contained in Paragraph 337 of Plaintiffs' Complaint.

338. Defendants deny the allegations contained in Paragraph 338 of Plaintiffs' Complaint.

PUNITIVE DAMAGES ALLEGATIONS

339. Defendants incorporate by reference their responses to Paragraphs 1-338 of Plaintiffs' Complaint as if fully set forth herein.

340. Defendants deny the allegations contained in Paragraph 340 of Plaintiffs' Complaint.

341. Defendants deny the allegations contained in Paragraph 341 of Plaintiffs' Complaint.

342. Defendants deny the allegations contained in Paragraph 342 of Plaintiffs' Complaint.

343. Defendants deny the allegations contained in Paragraph 343 of Plaintiffs' Complaint.

344. Defendants deny the allegations contained in Paragraph 344 of Plaintiffs' Complaint.

345. Defendants deny the allegations contained in Paragraph 345 of Plaintiffs' Complaint.

346. Defendants deny the allegations contained in Paragraph 346 of Plaintiffs' Complaint.

347. Defendants deny the allegations contained in Paragraph 347 of Plaintiffs' Complaint.

348. Defendants deny the allegations contained in Paragraph 348 of Plaintiffs' Complaint.

349. Defendants deny the allegations contained in Paragraph 349 of Plaintiffs' Complaint.

PRAYER FOR RELIEF

Furthermore, responding to the unnumbered Paragraph, including sub-parts numbered Paragraphs A-K, following the heading "PRAYER FOR RELIEF" and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph and sub-parts.

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiffs' Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiffs' damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiffs have been damaged, which Defendants deny, any recovery by Plaintiffs is barred to the extent Plaintiffs voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent Plaintiffs have failed to mitigate their alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

5. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiffs.

6. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

7. The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent federal statutes and regulations. Accordingly, Plaintiffs' claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

8. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.

9. There was no defect in the products at issue with the result that Plaintiffs are not entitled to recover against Defendants in this cause.

10. If there were any defect in the products – and Defendants deny that there were any defects – nevertheless, there was no causal connection between any alleged defect and the products on the one hand and any damage to Plaintiffs on the other with the result that Plaintiffs are not entitled to recover against Defendants in this cause.

11. Plaintiffs' injuries, losses or damages, if any, were caused by or contributed to by other persons or entities that are severally liable for all or part of Plaintiffs' alleged injuries, losses or damages. If Defendants are held liable to Plaintiffs, which liability is specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiffs' alleged damages.

12. Plaintiffs' claims are barred to the extent that the injuries alleged in the Plaintiffs' Complaint were caused by the abuse, misuse, abnormal use, or use of the products at issue in a manner not intended by Defendants and over which Defendants had no control.

13. Plaintiffs' claims are barred to the extent that the injuries alleged in the Plaintiffs' Complaint were caused by a substantial change in the products after leaving the possession, custody, and control of Defendants.

14. Plaintiffs' breach of warranty claims are barred because: (1) Defendants did not make any warranties, express or implied, to Plaintiffs; (2) there was a lack of privity between Defendants and Plaintiffs; and (3) notice of an alleged breach was not given to the seller or Defendants.

15. Plaintiffs' claims for breach of implied warranty must fail because the products were not used for its ordinary purpose.

16. Defendants neither had nor breached any alleged duty to warn with respect to the products, with the result that Plaintiffs are not entitled to recover in this cause.

17. Plaintiffs' claims are barred by Defendants' dissemination of legally adequate warnings and instructions to learned intermediaries.

18. At all relevant times herein, Plaintiffs' physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of the subject products.

19. If Plaintiffs have been damaged, which Defendants deny, the actions of persons or entities for whose conduct Defendants are not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the products and other independent causes, constitute an intervening and superseding cause of Plaintiffs' alleged damages.

20. To the extent that injuries and damages sustained by Plaintiffs, as alleged in Plaintiffs' Complaint, were caused directly, solely, and proximately by sensitivities, medical conditions, and idiosyncrasies peculiar to Plaintiffs not found in the general public, they were unknown, unknowable, or not reasonably foreseeable to Defendants.

21. Defendants believe, and upon that ground allege, that Plaintiffs were advised of the risks associated with the matters alleged in Plaintiffs' Complaint and knowingly and voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed consent, release, waiver, or comparative fault, this conduct bars in whole or in part the damages that Plaintiffs seek to recover herein.

22. At all relevant times during which the devices at issue were designed, developed, manufactured, and sold, the devices were reasonably safe and reasonably fit for their intended use, were not defective or unreasonably dangerous, and were accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

23. Plaintiffs' claims are barred because Plaintiffs suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

24. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver, estoppel, and/or laches.

25. If Plaintiffs suffered any damages or injuries, which are denied, Defendants state that Plaintiffs' recovery is barred, in whole or in part, or subject to reduction, under the doctrines of contributory and/or comparative negligence.

26. In the further alternative, and only in the event that it is determined that Plaintiffs are entitled to recover against Defendants, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to Plaintiffs, any other defendants, third-party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the future.

27. Should Defendants be held liable to Plaintiffs, which liability is specifically denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiffs from all collateral sources.

28. Plaintiffs' claims may be barred, in whole or in part, from seeking recovery against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of claims, and the prohibition on double recovery for the same injury.

29. The injuries and damages allegedly sustained by Plaintiffs may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiffs over which Defendants had no control.

30. The conduct of Defendants and all activities with respect to the subject product have been and are under the supervision of the Federal Food and Drug Administration ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

31. Defendants assert any and all defenses, claims, credits, offsets, or remedies provided by the Restatements (Second and Third) of Torts and reserve the right to amend their Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

32. The device at issue complied with any applicable product safety statute or administrative regulation, and therefore Plaintiffs' defective design and warnings-based claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and comments thereto.

33. Plaintiffs cannot show that any reasonable alternative design would have rendered Bard's Inferior Vena Cava Filters as alleged in Plaintiffs' Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could Defendants have known of any alternative design that may be identified by Plaintiffs.

34. The devices at issue were not sold in a defective condition unreasonably dangerous to the user or consumer, and therefore Plaintiffs' claims are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and comparable provisions of the Restatement (Third) of Torts (Products Liability).

35. At all relevant times during which the devices at issue were designed, developed, manufactured, and sold, the devices were reasonably safe and reasonably fit for their intended use, were not defective or unreasonably dangerous, and were accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

36. Defendants specifically plead all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

37. Plaintiffs' alleged damages, if any, should be apportioned among all parties at fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors Act.

38. No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

39. To the extent the claims asserted in Plaintiffs' Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate

Defendants' rights under the Constitution of the United States and analogous provisions of the various states' constitutions.

40. To the extent Plaintiffs' claims are based on alleged misrepresentations made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

41. Defendants are entitled to, and claim the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute that may be applicable.

42. Regarding Plaintiffs' demand for punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

43. Plaintiffs' claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and similar provisions of the various states' constitutions, on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and

Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendants, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

44. Plaintiffs have failed to plead their fraud claims with the particularity required under applicable state's statutory and/or common law.

45. Plaintiffs' cases may be subject to dismissal or transfer under the doctrine of forum non conveniens.

46. Plaintiffs' product liability claims are barred because the benefits of the products outweighed their risks.

47. Venue may be improper in any individual case where the plaintiff does not reside in the forum wherein his or her Complaint was filed or cannot otherwise establish an independent basis for venue in that forum and any such claims should be dismissed on this basis.

48. The damages claimed by Plaintiffs are not recoverable, in whole or in part, under the various applicable states' laws.

49. Plaintiffs' claims are barred, in whole or in part, to the extent Plaintiffs seek damages in excess of applicable state-law caps and limits on recovery of damages or of specific categories of damages.

50. Plaintiffs' claims are barred, in whole or in part, by insufficiency of service and/or insufficiency of service of process.

51. Defendants are entitled to and claim the benefits of all defenses and presumptions set forth in or arising from any rule of law or statute in this state or any other state whose law is deemed to apply in this case.

52. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiffs have failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

53. Defendants assert that choice of law rules should determine which jurisdiction's laws govern this case and expressly reserve the right to supplement this answer with any defenses that may be available to it under the law of the jurisdictions determined to apply to it in accordance with choice of law rules.

54. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiffs are not entitled to the relief demanded in the Plaintiffs' Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This _____ day of _____, 20__.

s/Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
Richard.North@nelsonmullins.com

James R. Condo (#005867)
Amanda Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren
Phoenix, AZ 85004-2204
PH: (602) 382-6000
JCondo@swlaw.com
ASheridan@swlaw.com

Attorney for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on [DATE], I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

s/Richard B. North, Jr.
Richard B. North, Jr.
Georgia Bar No. 545599
NELSON MULLINS RILEY & SCARBOROUGH, LLP
Atlantic Station
201 17th Street, NW / Suite 1700
Atlanta, GA 30363
PH: (404) 322-6000
FX: (404) 322-6050
Richard.North@nelsonmullins.com

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. MD-15-02641-PHX-DGC

AMENDED CASE MANAGEMENT ORDER NO. 5

(Plaintiff and Defendant Profile Forms)

The parties have agreed upon the use of an abbreviated Plaintiff Profile Form ("PPF") (Exhibit 1) attached to this Order. Except as expressly noted herein, the PPF shall be completed in each currently pending case, and in all cases that become part of this MDL by virtue of being filed in, removed to, or transferred to this Court on or after the date of this Order.

Each plaintiff in currently filed cases (except as noted herein) shall submit a completed PPF to defendants within 60 days of the date of this Order. In cases that have been filed in, removed to, or transferred to this MDL on or after the date of this Order, each plaintiff shall submit a completed PPF to defendants within 60 days of filing the complaint.

The completed PPF shall be delivered via email to: filterppf-pfs@nelsonmullins.com and to co-lead counsel via email at wespita@lopezmchugh.com and karin.scheehle@gknet.com .

Each plaintiff is required to provide defendants with a PPF that is substantially complete in all respects, answering every question in the PPF, even if a plaintiff can answer the question in good faith only by indicating "not applicable" or "unknown." The

PPF shall be signed by the plaintiff under penalty of perjury. If a plaintiff is suing in a representative or derivative capacity, the PPF shall be completed by the person with the legal authority to represent the estate or the person under legal disability. Plaintiff spouses with a claim for loss of consortium shall also sign the PPF, attesting that the responses made to the loss of consortium questions in the PPF are true and correct to the best of his or her knowledge, information and belief, formed after due diligence and reasonable inquiry.

A completed PPF shall be considered interrogatory answers under Fed. R. Civ. P. 33 and responses to requests for production under Fed. R. Civ. P. 34, and will be governed by the standards applicable to written discovery under Federal Rules 26 through 37. The interrogatories and requests for production in the PPF shall be answered without objection as to the question posed in the agreed upon PPF. This section does not prohibit a plaintiff from withholding or redacting information from medical or other records provided with the PPF based upon a recognized privilege. If information is withheld or redacted on the basis of privilege, plaintiff shall provide defendants with a privilege log that complies with Fed. R. Civ. P. 26(b)(5) simultaneously with the submission of the PPF.

If a plaintiff does not submit a PPF within the time specified in this Order, defendants shall mail an overdue letter by e-mail and U.S. mail to Plaintiffs' Co-Lead Counsel and the plaintiffs' individual representative counsel, stating that defendants may move to dismiss that plaintiff's case within 20 days of receipt of the letter. If no PPF is received within those 20 additional days, defendants may move immediately to dismiss that plaintiff's case. If defendants receive a PPF that is not substantially complete, defendants' counsel shall send a deficiency letter within 14 days of receipt of a PPF, as applicable by e-mail and U.S. mail to Plaintiffs' Co-Lead Counsel and the plaintiffs' individual representative counsel, identifying the purported deficiencies. Plaintiff shall have 20 days from receipt of that letter to serve a PPF that is substantially complete in all

respects. This letter shall include sufficient detail for the parties to meet and confer regarding the alleged deficiencies.

Within 45 days of receipt of a substantially complete PPF for an individual plaintiff, the defendants shall provide the plaintiff with a completed Defendants' Profile Form (DPF) (Exhibit 2) attached to this order. A completed DPF shall be considered interrogatory answers under Fed. R. Civ. P. 33 and responses to requests for production under Fed. R. Civ. P. 34, and will be governed by the standards applicable to written discovery under Federal Rules 26 through 37. The interrogatories and requests for production in the DPF shall be answered without objection as to the question posed in the agreed upon DPF. This section does not prohibit a defendant from withholding or redacting information from medical or other records provided with the DPF based upon a recognized privilege. If information is withheld or redacted on the basis of privilege, defendants shall provide plaintiff with a privilege log that complies with Fed. R. Civ. P. 26(b)(5) simultaneously with the submission of the DPF.

If the plaintiff receives a DPF that is not substantially complete, plaintiff's counsel shall send a deficiency letter within 14 days of receipt of a DPF, as applicable by e-mail and U.S. mail to Defendants' Lead Counsel identifying the purported deficiencies. Defendants shall have 20 days from receipt of that letter to serve a DPF that is substantially complete in all respects. This letter shall include sufficient detail for the parties to meet and confer regarding the alleged deficiencies.

The procedures outlined in this Order shall not apply to the following cases:

Plaintiff	Original Jurisdiction
1. Cason, Pamela	GA – N.D. Ga. 1:12-cv-1288
2. Coker, Jennifer	GA – N.D. Ga. 1:13-cv-515
3. Conn, Charles	TX – S.D. Tex. 4:14-cv-298

Plaintiff	Original Jurisdiction
4. Ebert, Melissa	PA – E.D. Pa. 5:12-cv-1253
5. Fox, Susan	TX – N.D. Tex. 3:14-cv-133
6. Henley, Angela	WI – E.D. Wis. 2:14-cv-59
7. Keen, Harry	PA – E.D. Pa. 5:13-cv-5361
8. Milton, Gary	GA – M.D. Ga. 5:14-cv-351
9. Mintz, Jessica	NY – E.D.N.Y. 2:14-v-4942
10. Ocasio, Denise	FL – M.D. Fla. 8:13-cv-1962
11. Rivera (McClarty), Vicki	MI – E.D. Mich. 4:14-cv-13627
12. Smith, Erin	TX – E.D. Tex. 1:13-cv-633
13. Tillman, Lessie	FL – M.D. Fla. 3:13-cv-222

The parties are relieved from preparing or exchanging profile forms in those particular cases.

Dated this 2nd day of March, 2016.

David G. Campbell
United States District Judge

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

MDL No. 2641
In Re Bard IVC Filter Products Liability Litigation

In completing this **Plaintiff Profile Form**, you are under oath and must provide information that is true and correct to the best of your knowledge. The Plaintiff Profile Form shall be completed in accordance with the requirements set forth in the applicable Case Management Order.

1. CASE INFORMATION

Caption: _____ **Date:** _____

Docket No.: _____

Plaintiff's attorney and Contact information:

_____

_____

_____

2. PLAINTIFF INFORMATION

Name: _____

Maiden Name: _____

Address: _____

Date of birth: _____

Social Security No.: _____

Occupation: _____

Spouse: _____

Is Spouse Making Claim for Loss of Consortium? ☐Yes ☐ No

3. DEVICE INFORMATION

A. **Filter Model (e.g., Recovery®, G2®, etc.):** _____
B. **Lot Number:** _____
C. **Date of Bard IVC Filter implant:** _____
D. **Attach medical evidence of product identification and operative report for filter placement.**

E. Please check all the reasons why you believe your Bard Filter was placed:

☐ Filter Placed After Being Diagnosed with Deep Vein Thrombosis/Pulmonary Embolism

☐ Filter Placed in Conjunction with or before Orthopedic Procedure

☐ Filter Placed in Conjunction with Trauma Situation/Motor vehicle accident

☐ Filter Placed in Conjunction with or before Bariatric Procedure

☐ Other Reason(s) for implant (explain): _____

_____

☐ Unknown

☐ See medical records attached

F. Provide the name and address of both the doctor who implanted the Bard Filter and the hospital or medical facility at which the filter was placed:

Doctor:_____

_____

Hospital/MedicalFacility:_____

_____

4. FAILURE MODE ALLEGED

Please check all failure mode(s) that you allege apply to your Bard Filter:

☐ Fracture

☐ Perforation of filter strut(s) into organs

☐ Migration of entire filter to heart

☐ Tilt with filter embedded in wall of the IVC

☐ Device unable to be retrieved

☐ Bleeding

☐ Other failure mode(s)

If other, please describe _____

_____

5. REMOVAL INFORMATION

A. Has your Bard Filter been removed?

☐Yes

☐ No

☐ Unknown

B. If your Bard Filter has been removed or a doctor has attempted to remove your Filter, please check all that apply regarding the removal or attempted removal procedure(s):

☐Removed percutaneously

☐ Removed via an open abdominal procedure

☐ Removed via an open chest procedure

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Unknown

☐ See medical records attached

C. Provide the name(s) and address(es) of both the doctor(s) who removed your Bard Filter (or attempted to remove it) and the hospital or medical facility where removal/attempted removal occurred:

Filter Removal/Attempted Removal #1

Doctor:_____

Hospital/MedicalFacility:_____

Filter Removal/Attempted Removal #2

Doctor:_____

Hospital/MedicalFacility:_____

6. FRACTURED STRUTS

A. Do you claim that your Bard Filter fractured?

☐ Yes

☐ No

If you answered YES, answer the below questions in this section.

If you answered NO, skip the rest of Section 6 and go below to section 7 - "Outcome Attributed to Device."

B. Are any fractured filter struts retained in your body?

☐ Yes

☐ No

☐ Unknown

If yes, identify the location(s) within your body of each retained filter strut.

_____

_____

C. Have any fractured filter struts been removed from your body?

☐ Yes

☐ No

☐ Unknown

D. If any fractured filter <u>strut</u> has been removed (or a doctor has attempted to remove any strut), please check <u>all</u> that apply regarding the removal / attempted removal procedure(s):

☐ Removed percutaneously

☐ Removed via an open abdominal procedure

☐ Removed via an open chest procedure

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe_____

☐ Unknown

E. Provide the name and address of both the doctor who removed (or attempted to remove) the <u>filter strut(s)</u> and the hospital or medical facility at which it was removed (or attempted to be removed)

Filter <u>Strut</u> Removal/Attempted Removal #1

Doctor:_____

Hospital/MedicalFacility:_____

Filter Strut Removal/Attempted Removal #2

Doctor:_____

Hospital/MedicalFacility:_____

7. OUTCOME ATTRIBUTED TO DEVICE

A. Do you claim to be suffering from any bodily injuries, including psychological injuries that are above and beyond usual pain and suffering and mental anguish, related to the Filter?

☐ Yes

☐ No

If your answer is "**Yes**," please list all symptoms and injuries you claim to have suffered :

_____

_____

Of the injuries/symptoms you listed above, which do you claim to be suffering from at the current time:

_____

_____

***

Plaintiff reserves the right to supplement any and all responses upon the receipt of additional information.

_____ _____

Date Signature of Plaintiff

_____ _____

Date Signature of Plaintiff – Spouse (signature only necessary if Loss of Consortium is alleged)

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION

MDL No. 2641

DEFENDANT BARD CASE PROFILE FORM

For each case, the Bard Defendants must complete this Defendant Profile Form ("DPF") in accordance with the schedule established by the Court's Pretrial Order. In completing this Profile Form, you must answer every question.

I. CASE INFORMATION

This defendant profile form pertains to the following case:

Case caption: _____

Civil Action No.: _____

Court in which action was originally filed: _____

II. CONTACTS WITH IMPLANTING AND REMOVING PHYSICIANS

Plaintiff has identified each healthcare provider who implanted, removed and/or attempted to remove Bard's Filter. With respect to each of those healthcare providers, provide the following information:

A. CONSULTATION AGREEMENT

1. As to the identified healthcare providers, state whether Bard has consulting agreement with the healthcare provider relating to IVC filters that Bard has been able to locate after a reasonable and diligent search.

_____

_____

B. SALES REPRESENTATIVE AND OTHER RELATED CONTACTS

As to each sales representative, territory manager and district manager who had any contact with an identified physician or healthcare provider, set forth the following:

1. Identity and last known address and telephone number of Representative(s):

_____

_____

As to the individual who Bard believes was the territory manager and district manger for the territory where the filter was implanted at the time of implant, set forth the following:

2. Identify the name of the territory manager and district manger, the dates of employment for each, and, if no longer employed by Bard, provide the last known address:

Territory Manager:

Name: _____

Employment Dates: _____

If former, last known address: _____

District Manager:

Name: _____

Employment Dates: _____

If former, last known address: _____

III. MANUFACTURING INFORMATION

A. Identify the lot number(s) for the Bard filter implanted in Plaintiff: _____

B. Identify the lot number for the Bard device used to remove or used to attempt to remove the Bard Filter implanted into Plaintiff:

_____

C. Identify the location and date of manufacture for each lot set forth in response to A and B above: _____

IV. DOCUMENTS

A. Please produce the following:

1. The Device History Record (DHR) for the Bard filter at issue, or, if already produced, provide the bates number for the DHR.

2. The Bard complaint file relating to plaintiff's claims, or, in the alternative if already produced, provide the bates number for the complaint.

3. The bates numbers for any documents previously produced that reference the implanting physician and/or the hospital or facility where the device as placed, that Bard is able to identify after a reasonable and diligent search.

4. Any consulting agreement relating to IVC filters that Bard has entered with the physician that implanted the filter.

5. With regard to the plaintiff, any Med Watch Adverse Event Reports in Bard's possession.

_____
Attorney for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

_____
[Signature]

WO

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. MD-15-02641-PHX-DGC

AMENDED CASE MANAGEMENT ORDER NO. 4

(Master Complaint, Master Responsive Pleading, Use of Short Form Complaint, Waiver of Service for Bard Defendants, and Answer and General Denial in Cases Subsequently Transferred to MDL 2641)

The parties have submitted a Master Long Form Complaint and Jury Demand (previously docketed as Doc. 303-1) and a Master Responsive Pleading (previously docketed as Doc. 303-3). The Court has reviewed these proposed pleadings, finds them sufficient, and directs the Clerk to file them as separate documents in the Court's docket.[1] The parties have also submitted a proposed Amended Short Form Complaint, a copy of which is attached to this order. The Court also finds these proposed pleadings to be sufficient.

IT IS ORDERED:

All allegations pled in the Master Complaint and all responses pled in the Master Responsive Pleading are deemed pled in any previously filed Complaint and Responsive Pleading in this MDL proceeding, except as expressly noted below. They are also deemed

[1] The reference to "Federal Rule of Evidence 8" on the first page of the Master Complaint shall be deemed to be a reference to Federal Rule of Civil Procedure 8.

pled in any Short Form Complaint (attached to CMO No. 4, Doc. 363) or Amended Short Form Complaint (attached to this Order) and Entry of Appearance filed after the entry of Doc. 363, except that the Master Complaint applies only against the Defendant or Defendants identified in such Short Form Complaints or Amended Short Form Complaints.

The following cases will not be governed by the Master Complaint and Master Responsive Pleading, but will continue to be governed by the complaints (including any amended complaints) and answers filed in the various transferor courts prior to transfer:

Plaintiff	Original Jurisdiction
1. Cason, Pamela	GA – N.D. Ga. 1:12-cv-1288
2. Coker, Jennifer	GA – N.D. Ga. 1:13-cv-515
3. Conn, Charles	TX – S.D. Tex. 4:14-cv-298
4. Ebert, Melissa	PA – E.D. Pa. 5:12-cv-1253
5. Fox, Susan	TX – N.D. Tex. 3:14-cv-133
6. Henley, Angela	WI – E.D. Wis. 2:14-cv-59
7. Keen, Harry	PA – E.D. Pa. 5:13-cv-5361
8. Milton, Gary	GA – M.D. Ga. 5:14-cv-351
9. Mintz, Jessica	NY – E.D.N.Y. 2:14-v-4942

Plaintiff	Original Jurisdiction
10. Ocasio, Denise	FL – M.D. Fla. 8:13-cv-1962
11. Rivera (McClarty), Vicki	MI – E.D. Mich. 4:14-cv-13627
12. Smith, Erin	TX – E.D. Tex. 1:13-cv-633
13. Tillman, Lessie	FL – M.D. Fla. 3:13-cv-222

On or after **December 28, 2015**, any plaintiff whose case would be subject to transfer to MDL 2641 may file his or her case directly in this Court by using the Short Form Complaint (Doc. 363). After **February 23, 2016**, Plaintiffs may use the Amended Short Form Complaint attached to this Order. If such a case is filed in this Court without the use of the Short Form Complaint or Amended Short Form Complaint, Plaintiffs' Co-Lead Counsel shall promptly advise the filing party to file an amended complaint using the Short Form Complaint or Amended Short Form Complaint. If the filing party fails to do so, Plaintiffs' Co-Lead Counsel shall promptly notify the Court.

Defendants are not required to file answers to Short Form Complaints or Amended Short Form Complaints. An Entry of Appearance shall constitute a denial of all allegations in the Short Form Complaints or Amended Short Form Complaints except as herein provided, and an assertion of all defenses included in the Master Responsive Pleading. By filing an Entry of Appearance in response to a Short Form Complaint or Amended Short Form Complaint, in lieu of an answer, Defendants do not waive any defenses, including jurisdictional and service defenses.

Civil actions in this MDL were transferred to this Court by the Judicial Panel on Multidistrict Litigation for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. Upon completion of the pretrial proceedings related to a civil action as

determined by this Court, the case shall be transferred pursuant to 28 U.S.C. § 1404(a) or § 1406(a) to the District Court identified in the Short Form Complaint or Amended Short Form Complaint, provided the parties choose not to waive *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). The fact that a case was filed directly in this District and MDL proceeding shall not constitute a determination by this Court that jurisdiction or venue are proper in this District, and shall not result in this Court being deemed the "transferor court" for purposes of this MDL. In addition, filing a Short Form Complaint or Amended Short Form Complaint in this District shall have no impact on the conflict of law rules to be applied to the case. Instead, the law of the jurisdiction where the case is ultimately transferred will govern any conflict of law. Prior to transfer, Defendants may object to the district specified in the Short Form Complaint or Amended Short Form Complaint, based on venue or jurisdiction (including a lack of personal jurisdiction based on *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014)), and propose an alternative jurisdiction for the Court's consideration.

Subject to the conditions set forth in this order, Defendant C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") waive service of process in cases filed in this Court using the Short Form Complaint or Amended Short Form Complaint and in which they are named as defendants and one or more IVC filter products either manufactured or distributed by Bard is alleged to be at issue. For such cases, Plaintiffs shall send a Short Form Complaint or Amended Short Form Complaint and a request for waiver of service pursuant to the provisions of Fed. R. Civ. P. 4 to Richard B. North, Jr. by email to richard.north@nelsonmullins.com; maria.turner@nelsonmullins.com; and matthew.lerner@nelsonmullins.com. Counsel for Bard shall return the signed waiver requests to the Court within the time permitted by Fed. R. Civ. P. 4. Plaintiffs submitting a request for waiver shall not seek to hold Bard in default for failure to timely answer or otherwise respond to a complaint in which service has been accomplished pursuant to the

terms of this order without first giving Bard written notice of the alleged default and ten business days in which to cure any alleged default.

Prior to a Plaintiff's attorney filing a Short Form Complaint or Amended Short Form Complaint in this Court, that attorney must register for or already have a District of Arizona CM/ECF log-in name and password. If the Plaintiff's attorney does not already have a District of Arizona CM/ECF log-in name and password, that attorney **must** file the Short Form Complaint or Amended Short Form Complaint in paper form with the Clerk of Court and simultaneously file an Application of Attorney for Admission to Practice Pro Hac Vice pursuant to LRCiv 83.1(b)(2) (including all necessary attachments and filing fee).

Additionally, with respect to cases which are originally filed in courts other than this Court which are then subsequently transferred to MDL 2641 pursuant to 28 U.S.C. § 1407, Defendants may file an Answer and General Denial with Respect to Cases Subsequently Transferred to MDL 2641, incorporating the defenses and denials set forth in the Master Responsive Pleading and generally denying the plantiffs' allegations. This short-form answer shall serve as the responsive pleading. Defendants shall have 60 days from the date any such case is opened in this Court to file any motion for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6) and 12(h)(2), and the plaintiff(s) shall have 30 days to respond.

Dated this 16th day of March, 2016.

David G. Campbell
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC **AMENDED MASTER SHORT FORM COMPLAINT FOR DAMAGES FOR INDIVIDUAL CLAIMS AND DEMAND FOR JURY TRIAL**

Plaintiff(s) named below, for their Complaint against Defendants named below, incorporate the Master Complaint for Damages in MDL 2641 by reference (Doc. 364). Plaintiff(s) further show the Court as follows:

1. Plaintiff/Deceased Party:

_____

2. Spousal Plaintiff/Deceased Party's spouse or other party making loss of consortium claim:

_____

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator):

_____

4. Plaintiff's/Deceased Party's state(s) [if more than one Plaintiff] of residence at the time of implant:

_____

5. Plaintiff's/Deceased Party's state(s) [if more than one Plaintiff] of residence at the time of injury:

_____

6. Plaintiff's current state(s) [if more than one Plaintiff] of residence:

_____

7. District Court and Division in which venue would be proper absent direct filing:

_____

8. Defendants (check Defendants against whom Complaint is made):

□ C.R. Bard Inc.

□ Bard Peripheral Vascular, Inc.

9. Basis of Jurisdiction:

□ Diversity of Citizenship

□ Other: _____

a. Other allegations of jurisdiction and venue not expressed in Master Complaint:

_____

_____

_____

10. Defendants' Inferior Vena Cava Filter(s) about which Plaintiff(s) is making a claim (Check applicable Inferior Vena Cava Filter(s)):

□ Recovery® Vena Cava Filter

□ G2® Vena Cava Filter

□ G2® Express (G2®X) Vena Cava Filter

□ Eclipse® Vena Cava Filter

□ Meridian® Vena Cava Filter

□ Denali® Vena Cava Filter

□ Other: _____

11. Date of Implantation as to each product:

_____

_____

12. Counts in the Master Complaint brought by Plaintiff(s):

□ Count I: Strict Products Liability – Manufacturing Defect

□ Count II: Strict Products Liability – Information Defect (Failure to Warn)

□ Count III: Strict Products Liability – Design Defect

□ Count IV: Negligence - Design

□ Count V: Negligence - Manufacture

□ Count VI: Negligence – Failure to Recall/Retrofit

□ Count VII: Negligence – Failure to Warn

□ Count VIII: Negligent Misrepresentation

□ Count IX: Negligence *Per Se*

□ Count X: Breach of Express Warranty

□ Count XI: Breach of Implied Warranty

□ Count XII: Fraudulent Misrepresentation

□ Count XIII: Fraudulent Concealment

□ Count XIV: Violations of Applicable _____ (insert state) Law Prohibiting Consumer Fraud and Unfair and Deceptive Trade Practices

□ Count XV: Loss of Consortium

□ Count XVI: Wrongful Death

□ Count XVII: Survival

□ Punitive Damages

□ Other(s): _____ (please state the facts supporting this Count in the space immediately below)

_____

_____

_____

_____

_____

13. Jury Trial demanded for all issues so triable?

□ Yes

□ No

RESPECTFULLY SUBMITTED this ____ day of March, 2016.

[SIGNATURE BLOCK]

By: */s/*
[Attorney name/address]

I hereby certify that on this ____ day of March, 2016, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/

5220248v1/26997-0001

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

MDL No. 2641
In Re Bard IVC Filter Products Liability Litigation

PLAINTIFF FACT SHEET

Each plaintiff who allegedly suffered injury as a result of a Bard Inferior Vena Cava Filter must complete the following Plaintiff Fact Sheet ("Plaintiff Fact Sheet"). In completing this Fact Sheet, you are **under oath and must answer every question.** You must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details as requested, please provide as much information as you can and then state that your answer is incomplete and explain why, as appropriate. If you select an "I Don't Know" answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact Sheet for himself/herself, please answer as completely as you can.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and responses to requests for production pursuant to Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. Therefore, you must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production of documents contained in this Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Bard Defendants from seeking additional documents and information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

In filling out this form, "healthcare provider" shall mean any medical provider, doctor, physician, surgeon, pharmacist, hospital, clinic, medical center, physician's office, infirmary, medical/diagnostic laboratory, or any other facility that provides medical care or advice, along with any pharmacy, x-ray department, radiology department, laboratory, physical therapist/physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in your diagnosis, care and/or treatment.

In filling out this form, the terms "You" or "Your" refer to the person who received a Bard Inferior Vena Cava Filter manufactured and/or distributed by C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. ("Bard Defendants") and who is identified in Question 1(a) below.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary, Information provided by Plaintiff will only

be used for the purposes related to this litigation and may be disclosed only as permitted under the protective order in this litigation.

I. BACKGROUND INFORMATION

1. Please state:

   (a) Full name of the person who received the Bard inferior vena cava filter, including maiden name:_____

   (b) List all names by which you have ever been known, if different from that listed in 1(a):_____

   _____

   (c) Full name of the person completing this form, if different from the person listed in 1(a) above, and the relationship of the person completing this form to the person listed in 1(a) above: _____

   (d) The name and address of your primary attorney:

   _____

   _____

   _____

   _____

   (e) When did you first retain an attorney to represent you in your lawsuit against Bard? _____

2. Your Social Security Number: _____

3. Your Date of Birth: _____

4. Your current residential address:

   _____

   _____

   _____

   _____

5. If you have lived at this address for less than 10 years, provide each of your prior residential addresses from 2000 to the present:

Prior Residential Address	Dates You Lived At This Address

6. Have you ever been married? Yes_____ No_____

If yes, provide the names and addresses of each spouse and the inclusive dates of your marriage to each person:

_____

_____

_____

7. Do you have children? Yes_____ No_____

If Yes, please provide the following information with respect to each child:

Full Name of Child	Date of Birth	Home Address	Whether Biological/Adopted

8. Identify the name and age of any person who currently resides with you and their relationship to you:

_____

_____

_____

9. Identify the name and age of any person who has resided with you at any point over the past ten (10) years:

_____

_____

_____

10. Identify all secondary and post-secondary schools you attended, starting with high school, and please provide the following information with respect to each:

Name of School	Address	Dates of Attendance	Degree Awarded	Major or Primary Field of Study

11. Please provide the following information for your employment history over the past 10 years up until the present:

Employer Name	Address	Job Title/Description of Duties	Dates of Employment	Salary/Rate of Pay

12. Have you ever served in any branch of the military? Yes_____ No_____

If Yes, please provide the following information:

(a) Branch and dates of service, rank upon discharge, and type of discharge received:

_____

(b) Were you discharged from the military at any time for any reason relating to your medical, physical, or psychiatric condition? Yes_____ No_____

If Yes, state what that condition was:_____

_____

13. Within the last ten years, have you been convicted of, or plead guilty to, a felony and/or crime of fraud or dishonesty? Yes_____ No_____

If Yes, please set forth where and when and identify the felony and/or crime:

_____

_____

_____

14. Before contacting any attorney regarding this lawsuit or claim, had you ever seen any television or print advertisements regarding possible claims against inferior Vena Cava Filter manufacturers?

Yes_____ No_____

If Yes, set forth the approximate date and nature of any such advertisement, whether the advertisement included the name of a law firm, whether the advertisement specifically mentioned C. R. Bard, Inc., Bard Peripheral Vascular, Inc., or "Bard", and other details that you recall. _____

_____

_____

_____

II. CLAIM INFORMATION

1. Have you ever received a Bard Inferior Vena Cava Filter? Yes_____ No_____

If Yes, please check the box(es) for each type of Bard Inferior Vena Cava Filter you have received:

☐ Recovery®

☐ G2®

☐ G2®X

☐ G2®Express

☐ Eclipse®

☐ Meridian®

☐ Denali®

☐ Other (please identify):_____

2. For each Bard Inferior Vena Cava Filter identified above, please provide the following information:

(a) The date each Bard Inferior Vena Cava Filter was implanted in you:

_____

(b) The product code and lot number of each Bard Inferior Vena Cava Filter implanted in you:

_____

(c) Current location of the Bard Inferior Vena Cava Filter, including any portion thereof, if known:

_____

_____

_____

3. Describe your understanding of the medical condition for which you received the Bard Inferior Vena Cava Filter(s):

_____

_____

4. Give the name and address of the doctor who implanted the Bard Inferior Vena Cava Filter(s):_____

_____

5. Give the name and address of the hospital or other healthcare facility where the Bard Inferior Vena Cava Filter was implanted:_____

_____

6. Have you ever been implanted with any other vena cava filters or related product(s) besides the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar condition(s) identified in your response to question 3 above? Yes_____ No_____

If Yes:

(a) Please identify any such device(s) or product(s)._____

_____

(b) When was this device or product implanted in you?_____

_____

(c) Did the implantation take place before, at the same time, or after the procedure during which you were implanted with a Bard Inferior Vena Cava Filter?

_____

_____

(d) Who was the physician who implanted this other device or product?

_____

_____

(e) At what hospital or facility was this other device or product implanted in you?

_____

_____

(f) Why was this other device or product implanted in you?

_____

_____

7. Prior to implantation with a Bard Inferior Vena Cava Filter, did you receive any written and/or verbal information or instructions regarding the Bard Inferior Vena Cava Filter, including any risks or complications that might be associated with the use of the same?

Yes_____ No_____ Don't Know_____

If Yes:

(a) Provide the date you received the written and/or verbal information or instructions:

_____

_____

(b) Identify by name and address the person(s) who provided the information and instructions:

_____

_____

(c) What information or instructions did you receive?

_____

_____

(d) If you have copies of the written information or instructions you received, please attach copies to your response.

_____

_____

(e) Were you told of any potential complications from the implantation of the Bard Inferior Vena Cava Filter(s)? Yes _____ No _____ Don't Know _____

(f) If yes to (e), by whom?

_____

_____

(g) If yes to (e), what potential complications were described to you?

_____

_____

8. Do you believe that the Bard Inferior Vena Cava Filter(s) remains implanted in you?

Yes _____ No _____ Don't Know _____

If Yes:

(a) Has any doctor recommended removal of the Bard Inferior Vena Cava Filter(s)?

Yes _____ No _____

If Yes:

(i) Identify by name and address every doctor who recommended removal of the Bard Inferior Vena Cava Filter(s):_____

_____

_____

(ii) For each doctor identified in response to question 8(a)(i) above, state your understanding of why the doctor recommended removal._____

_____

_____

(iii) For each doctor identified in response to question 8(a)(i) above, state when the doctor recommended removal._____

_____

_____

9. Has the Bard Inferior Vena Cava Filter(s) implanted in you been removed, in whole or in part?

Yes_____ No_____ Don't Know_____

If Yes:

(a) Where, when, and by whom was the Bard Inferior Vena Cava Filter(s), or any portion of it, removed?_____

_____

_____

(b) What portion of the Bard Inferior Vena Cava Filter(s) was removed on the date indicated in response to question 9(a) above?_____

_____

_____

(c) Please check all that apply regarding the removal procedure(s):

☐ Removed percutaneously

☐ Removed via an open abdominal procedure

☐ Removed via an open chest procedure

☐ Other, Describe: _____

☐ Unknown

(d) Does any portion of the Bard Inferior Vena Cava Filter(s) remain implanted in you? Yes _____ No _____ Don't Know _____

If Yes, explain what portion of the Bard Inferior Vena Cava Filter(s) you believe is still implanted in you:_____

_____

_____

(e) Explain why you consented to have the Bard Inferior Vena Cava Filter(s), or any portion thereof, removed?

_____

_____

_____

(f) Does any medical provider, physician, entity, or anyone else acting on your behalf have possession of any portion of the Bard Inferior Vena Cava Filter that was previously implanted in you and subsequently removed?

Yes_____ No_____ Don't Know_____

If Yes, please state the name and address of the person or entity having possession of same._____

_____

10. Has any doctor or healthcare provider unsuccessfully attempted to remove the Bard Inferior Vena Cava Filter(s) implanted in you?

Yes_____ No_____ Don't Know_____

If Yes:

(a) How many attempts have been made to remove the Bard Inferior Vena Cava Filter(s) implanted in you?_____

(b) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).

Filter Removal/Attempted Removal #1

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

Filter Removal/Attempted Removal #2

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

Filter Removal/Attempted Removal #3

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

(c) Please check all that apply regarding attempted removal procedure #1:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

_____

☐ Unknown

(d) Please check all that apply regarding attempted removal procedure #2:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

_____

☐ Unknown

(e) Please check all that apply regarding attempted removal procedure #3:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

_____

☐ Unknown

11. Do you claim that your Bard Inferior Vena Cava Filter(s) fractured?

Yes_____ No_____

If Yes:

(i) Please state the number of fractured struts retained in your body?

_____

(ii) Please identify the location(s) within your body of each retained filter strut.

_____

_____

(iii) Please provide the date or approximate date when you were first informed of each fractured strut.

_____

_____

(iv) Has any health care provider recommended to you that a retained filter strut(s) should be removed?

Yes _____ No_____

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

_____

_____

_____

(v) Has any health care provider recommended to you that a retained filter strut should <u>not</u> be removed?

Yes_____ No_____

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

_____

_____

_____

(vi) Have any fractured struts been removed, or attempted to have been removed, from your body?

Yes _____ No_____

If Yes:

(1) If any fractured filter strut has been removed (or a doctor has attempted to remove any strut), please check <u>all</u> that apply regarding the removal/attempted removal procedure(s):

☐ Removed percutaneously

☐ Removed via an open abdominal procedure

☐ Removed via an open chest procedure

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

☐ Unknown

(2) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).

Filter *Strut* Removal/Attempted Removal #1

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

Filter *Strut* Removal/Attempted Removal #2

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

12. Do you claim that you suffered bodily injuries as a result of the implantation of the Bard Inferior Vena Cava Filter(s)? Yes_____ No_____

If Yes:

(a) Describe the bodily injuries, including any emotional or psychological injuries that you claim resulted from the implantation, attempted removal and/or removal of the Bard Inferior Vena Cava Filter(s)?_____

_____

_____

(b) When was the first time you experienced symptoms of any of the bodily injuries you claim in your lawsuit to have resulted from the Bard Inferior Vena Cava Filter(s)?

_____

_____

(c) When did you first attribute these bodily injuries to the Bard Inferior Vena Cava Filter(s)?_____

_____

(d) To the best of your knowledge and recollection, please state the approximate date when you first saw a health care provider for any of the bodily injuries, or symptoms related thereto, you claim to have experienced related to the Bard Inferior Vena Cava Filter(s)?

_____

_____

_____

(e) To the best of your knowledge and recollection, has any health care provider ever told you orally or in writing that any symptoms related to bodily injury are related to the Bard Inferior Vena Cava Filter(s)?

Yes_____ No_____

If Yes, please state the name and address of any such health care provider, as well as providing the approximate date the statement was made, and provide the details of the communication:_____

_____

_____

_____

_____

(f) Are you currently experiencing symptoms related to your claimed bodily injuries?

Yes_____ No_____

If Yes, please describe your symptoms in detail:

_____

_____

(g) Are you currently seeing, or have you ever seen, a doctor or healthcare provider for any of the bodily injuries or symptoms listed above?

Yes_____ No _____

If Yes, please list all doctors you have seen for treatment of any of the bodily injuries you have listed above.

Provider Name and Address	Condition Treated	Approximate Dates of Treatment

h) Were you hospitalized at any time for the bodily injuries you listed above?

Yes _____ No_____

If Yes, please provide the following:

Hospital Name and Address	Condition Treated	Approximate Dates of Treatment

13. Are you making a claim for lost wages or lost earning capacity?

Yes_____ No_____

(a) If yes, state the annual gross income derived from your employment for each year, beginning five (5) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) until the present: _____

_____

_____

(b) If yes, for what period of time are you claiming lost wages?_____

_____

_____

(c) If you are claiming lost earning capacity, do you claim that you have a claim for future lost wages?

Yes_____ No_____

If yes, for what period of time do you claim you have lost future wages?

_____

_____

_____

14. Are you making a claim for lost out-of-pocket expenses? Yes_____ No_____

If yes, please identify and itemize all out-of-pocket expenses you have incurred.

_____

_____

_____

15. Has anyone filed a loss of consortium claim in connection with your lawsuit regarding the Bard Inferior Vena Cava Filter(s)?

Yes_____ No_____

If yes, identify by name and address the person who filed the loss of consortium claim ("Consortium Plaintiff") and state the relationship of that person to you and state the specific nature of the Consortium Plaintiff's claim._____

_____

_____

_____

16. Please indicate whether the Consortium Plaintiff alleges any of the damages set forth below:

Claims	Yes/No
Loss of services of spouse	
Impaired sexual relations	
Lost wages/lost earning capacity	
Lost out-of-pocket expenses	
Physical injuries	
Psychological injuries/emotional injuries	
Other	

17. Please list the name and address of any healthcare providers the Consortium Plaintiff has sought treatment for any physical, emotional, or psychological injuries or symptoms alleged to be related to his/her claim._____

_____

_____

_____

18. Have you or anyone acting on your behalf had any communication, oral or written, with any of the Bard Defendants and/or their representatives?

Yes _____ No_____ Don't Know _____

If yes, set forth: (a) the date of any communication, (b) the method of communication, (c) the name of the person with whom you communicated, and (d) the substance of the communications._____

_____

_____

III. MEDICAL BACKGROUND

1. Provide your current: Age_____ Height_____ Weight_____
2. Provide your: Age_____ Weight_____ (approximate, if unknown) at the time the Bard Inferior Vena Cava Filter was implanted in you.
3. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had in the ten (10) year period BEFORE implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

Approximate Date	Description of Surgery or Hospitalization	Doctor or Healthcare Provider Involved (including address)

[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations leading up to the implantation of the Bard Inferior Vena Cava Filter.]

4. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had AFTER implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

Approximate Date	Description of Surgery or Hospitalization	Doctor or Healthcare Provider Involved (including address)

[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations after the implantation of the Bard Inferior Vena Cava Filter.]

5. To the extent not already provided in the charts above, provide the name, address, and telephone number of every doctor, hospital or other health care provider from which you have received medical advice and/or treatment from ten (10) years before the date the filter was implanted to the present:

Name and Specialty	Address	Approximate Date/Years of Visits

6. *Before the implantation* of the Bard Inferior Vena Cava Filter(s), did you regularly exercise or participate in activities that required lifting or strenuous physical activity? (Please include all physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

Yes _____ No _____

If yes, please describe each activity in detail. _____

_____

_____

_____

7. *Since the implantation* of the Bard Inferior Vena Cava Filter(s), have you regularly exercised or participated in activities that required lifting or strenuous physical activity? (Please describe all range of physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

Yes _____ No _____

If yes, please describe each activity in detail. _____

_____

_____

_____

8. During the past ten (10) years, what have been your primary hobbies or recreational activities? _____

_____

_____

_____

(a) Do you claim that you are unable to participate in any of the hobbies or recreational activities listed in response to question 8 above as a result of you having been implanted with a Bard Inferior Vena Cava Filter(s)?

Yes_____ No_____

(b) If yes, what hobbies or recreational activities do you claim that you are unable to participate in as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)?_____

_____

_____

(c) For what period of time do you claim that you were or have been unable to participate in any hobbies or recreational activities as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)?

_____

_____

_____

9. To the best of your knowledge, have you ever been told by a doctor or another health care provider that you have suffered, may have suffered, or presently do suffer from any of the following:

_____ Lupus

_____ Crohn's Disease

_____ Factor V Leiden

_____ Protein Deficiency

_____ Spinal Fusion or Other Back Procedures

_____ Anti-thrombin Deficiency

_____ Prothrombin Mutation

_____ Deep Vein Thrombosis

_____ Pulmonary Embolism

_____ Auto Immune Disorder

_____ Varicose Veins

_____ Heart Procedures

_____ Blood Disorder

Please Describe:_____

_____ Bariatric Surgery

_____ Anticoagulation Medication (e.g., Coumadin, Warfarin, etc.)

_____ Ulcerative Colitis/Inflammatory Bowel Disease (IBD)

_____ Cancer

Please Describe:_____

* * * * * * * * * *

THE FOLLOWING QUESTIONS ARE CONFIDENTIAL AND SUBJECT TO THE PROTECTIVE ORDER APPLICABLE TO THIS CASE.

(A) Have you been diagnosed with and/or treated for any drug, alcohol, chemical and/or other addiction or dependency during the five (5) years prior to the filing of this lawsuit through the present? Yes_____ No_____

If yes, specify type and time period of dependency, type of treatment received, name of treatment provider, and current status of condition:

_____

_____

_____

_____

(B) Have you experienced, been diagnosed with or received psychiatric or psychological treatment of any type, including therapy, for any mental health conditions including depression, anxiety, or other emotional or psychiatric disorders during the five (5) years prior to the filing of this lawsuit through the present? Yes_____ No_____

If yes, specify condition, date of onset, medication/treatment, treating physician and current status of condition:

_____

_____

_____

_____

* * * * * * * * * *

10. Do you now or have you ever smoked tobacco products? Yes_____ No_____

If yes:

How long have/did you smoke?_____

11. Other than the implantation of the Bard Inferior Vena Cava Filter device that is the subject of your lawsuit, are you aware of any other Vena Cava Filter(s) implanted inside your body at any time? Yes_____ No_____

If yes, please provide the following information:

(a) Product name:_____

(b) Date of procedure placing it and name and address of doctor who placed it:

_____

(c) Condition sought to be treated through placement of the device:

_____

(d) Any complications you encountered with the medical product or procedure:

_____

(e) Does that product remain implanted inside of you today? Yes_____ No_____

12. List each prescription medication you have taken for more than three (3) months at a time during the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present, giving the name and address of the pharmacy where you received/filled the medication, the reason you took the medication, and the approximate dates of use.

Medication and Dosage	Prescribing Physician	Pharmacy Name and Address	Reason for Taking Medication	Approximate Date(s) of Use

IV. INSURANCE INFORMATION

1. Provide the following information for any past or present medical insurance coverage from the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present:

Insurance Company Name and Address	Policy Number	Name of Policy Holder/Insured (if different than yourself)	Approximate Dates of Coverage

2. To the best of your knowledge, have you ever been approved to receive or are you currently receiving Medicare/Medicaid benefits due to age, disability, condition, or any other reason or basis?

Yes_____ No_____

If yes, please specify the date on which you first became eligible:_____

[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]

V. PRIOR CLAIM INFORMATION

1. Have you filed a lawsuit or made a claim in the last ten (10) years, other than in the present suit relating to any bodily injury?

Yes_____ No_____

If yes, please specify the following:

(a) Court in which the lawsuit/claim was filed or initiated:_____

_____

(b) Case/Claim Number:_____

(c) Nature of Claim/Injury:_____

_____

2. Have you ever applied for Workers' Compensation (WC), Social Security disability (SSI or SSD) benefits, or other State or Federal disability benefits?

Yes_____ No_____

If yes, please specify the following:

(a) Date (or year) of application:_____

(b) Type of benefits sought:_____

(c) Agency/Insurer from which you sought the benefits:_____

_____

(d) Nature of the claimed injury/disability:_____

_____

(e) Whether the claim was accepted or denied:_____

VI. FACT WITNESSES

1. Identify by name, address, and relationship to you, all persons (other than your healthcare providers) who possess information concerning your injuries and/or current medical condition:

Name	Address	Relationship to You	Information You Believe Person Possesses

VII. IDENTIFICATION OF DOCUMENTS AND OTHER ELECTRONICALLY STORED INFORMATION

For the period beginning three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter until the present, please identify all research, including on-line research, that you conducted regarding the medical complaints or condition for which you received the Bard Inferior Vena Cava Filter (pulmonary thromboembolism, anticoagulant therapy, etc.) Identify the date, time, and source, including any websites visited. (Research conducted subsequent to and for the purpose of understanding the legal and strategic advice of your counsel is not considered responsive to this request.)

_____

_____

_____

_____
_____
_____
_____

VIII. DOCUMENT REQUESTS

1. RELEASES.

NOTE: Please sign and attach to this Fact Sheet the authorizations for the release of records appended hereto.

2. DOCUMENTS. State whether you have any of the following documents in your possession, custody, and/or control. If you do, please provide a true and correct copy of any such documents with this completed Fact Sheet.

(a) If you were appointed by a Court to represent the plaintiff in this lawsuit, produce any documents demonstrating such appointment.

(i) Not applicable _____

(ii) The documents are attached_____ [OR] I have no documents_____

(b) If you represent the Estate of a deceased person in this lawsuit, produce a copy of the decedent's death certificate and autopsy report (if applicable).

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(c) Produce each and every medical record of each and every medical facility, pharmacy, or practitioner of the healing arts identified by you in response to the questions in Sections II and III above regarding your medical care and history for the time period beginning ten (10) years prior to the implantation of the Bard Inferior Vena Cava Filter and continuing to the present.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(d) Produce any communication (sent or received) in your possession, which shall include materials accessible to you from any computer on which you have sent or received such communications, concerning the Bard Inferior Vena Cava Filter(s) or subject of this litigation, including, but not limited to all letters, emails, blogs, Facebook posts, Tweets, newsletters, etc. sent or received by you. (Research

conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(e) Produce all documents, including journal entries, lists, memoranda, notes, diaries, photographs, video, DVDs or other media, discussing or referencing the Bard Inferior Vena Cava Filter(s), the injuries and/or damages you claim resulted from the Bard Inferior Vena Cava Filter(s), and/or evidencing your physical condition from three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) to present. (Research conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(f) Produce any Bard Inferior Vena Cava Filer product packaging, labeling, advertising, or any other product-related items in your possession, custody or control.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(g) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) and the Food and Drug Administration (FDA), or between you and any employee or agent of the Bard Defendants, regarding Bard Inferior Vena Cava Filters.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(h) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to the Food and Drug Administration (FDA) and/or the Department of Health and Human Services regarding Bard Inferior Vena Cava Filters.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(i) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) with anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(j) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(k) Produce all documents in your possession, custody, or control evidencing or relating to any correspondence or communication between C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. (or any related companies or divisions) and any of your doctors, healthcare providers, and/or you relating to Bard Inferior Vena Cava Filters, except as to those communications which are protected by the attorney-client privilege or attorney work product doctrine.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(l) Produce all documents in your possession, custody, or control reflecting, describing, or in any way relating to any instructions or warnings you received prior to implantation of any Inferior Vena Cava Filter(s) concerning the risks and/or benefits associated with Inferior Vena Cava Filter(s), including but not limited to the Bard Inferior Vena Cava Filter implanted in you.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(m) Produce any and all documents reflecting the model number and lot number of the Bard Inferior Vena Cava Filter(s) you received.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(n) If you underwent surgery or any other procedure to remove, in whole or in part, the Bard Inferior Vena Cava Filter(s), produce any and all documents, other than documents that may have been generated by expert witnesses retained by your counsel for litigation purposes, that relate to any evaluation of the Bard Inferior Vena Cava Filter(s) removed from you.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(o) Produce all documents in your possession, custody, or control concerning payment by Medicare on behalf of the injured party and relating to the injuries claimed in this lawsuit. This includes, but is not limited to Interim Conditional Payment summaries and/or estimates prepared by Medicare or its representatives regarding payments made on your behalf for medical expenses relating to the subject of this litigation.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]

(q) Produce all screenshots of all webpages of each type of social media used by you (including, but not limited to, Facebook, Twitter, Instagram, Vine, Snapchat, YouTube, LinkedIn) showing any and all "posts" and/or "messages" from the date of implantation to the present.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(r) Produce the Bard Inferior Vena Cava Filter(s) or any and all components thereof previously implanted in you.

VERIFICATION

I, _____, declare under penalty of perjury, subject to all applicable laws and in the presence of the below named witness, that I have carefully reviewed the final copy of this Plaintiff Fact Sheet dated _____ and verified that all of the information provided is true and correct to the best of my knowledge, information and belief.

_____ _____

Signature of Witness Signature of Plaintiff

_____

Name of Witness

_____

Address of Witness

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS
PRODUCT LIABILITY LITIGATION

MDL No. 2641

This Document Relates:

Case No:_____

DEFENDANT FACT SHEET

For each case, the Bard Defendants must complete this Defendant Fact Sheet ("DFS") in accordance with the schedule established by the Court's Pretrial Order.

The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. Therefore, you must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production of documents contained in this Fact Sheet are non-objectionable and shall be answered without objection, except that Defendants may assert, where appropriate, objections based on privilege or work product grounds; in which case they will produce a privilege log. This Fact Sheet shall not preclude Plaintiffs from seeking additional documents and information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

This DFS must be completed and served on all counsel representing a plaintiff in the action identified in Section I below, as well as Co-Lead Counsel for PLC, Ramon Rossi Lopez and Robert W. Boatman. Complete fact sheets must be answered and served in accordance with the Case Management Plan to be entered by this Court.

Each document request and interrogatory not only calls for knowledge but also for all knowledge that is available to you by reasonable inquiry, including inquiry of your officers, directors, employees, contractors and agents.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary. Please identify any documents that you are producing responsive to a question with Bates-Stamp identifiers.

In filling out this form, "document" and "documents" mean and refer to a writing and/or recording as defined by Federal Rule 34, including, without limitation, the following terms in their broadest sense, whether printed or recorded or reproduced by any other mechanical process, or written or produced by hand: agreements, "communications", State and Federal governmental hearings and reports, correspondence, telegrams, memoranda, summaries or records of telephone conversations, summaries or records of personal conversations or interviews, diaries, graphs, reports, notebooks, note charts, plans, drawings, sketches, maps, summaries or records of meetings or conferences, summaries or reports of investigations or negotiations, opinions or reports of consultants, radiographs, photographs, motion picture films, brochures, pamphlets, advertisements, circulars, press releases, drafts, letters, any marginal comments appearing on any document, and all other writings.

In filling out this form, the word "communication and/or "correspondence" shall mean and refer to any oral, written, spoken, or electronic transmission of information, including, but not limited to, meetings, discussions, conversations, telephone calls, memoranda, letters, emails, text messages, postings, instructions, conferences, seminars, or any other exchange of information between Defendants and any other person or entity.

In filling out this form, "healthcare provider" shall mean any doctor, physician, or surgeon who treated the plaintiff for deep vein thrombosis, pulmonary embolism, or associated conditions, or who prescribed or implanted a Bard IVC Filter, who removed or attempted to remove a Bard IVC Filter. In filling out this form, the terms "You", "Your", or "Yours" refer to the person who sold, marketed, researched, designed, manufactured, consulted, or represented a Bard Inferior Vena Cava Filter manufactured and/or distributed on behalf of C.R. Bard Inc. "Bard Defendants" and who is identified in Question I below.

In filling out this form, "key opinion leader" or "thought leader" shall mean and refer to physicians, who are believed by Defendants to be effective at transmitting messages to their peers and others in the medical community. This term shall mean and refer to any doctors or medical professionals hired by, consulted with, or retained by Defendants to, amongst other things, consult, give lectures, respond to media inquiries, conduct clinical trials, write articles or abstracts, sign their names as authors to articles or abstracts written by others, and occasionally make presentations on their behalf at regulatory meetings or hearings, association meetings, hospital department meetings, or other professional meetings including local, regional and national meetings, and any other meeting organized and planned by or on behalf of Defendants.

I. CASE INFORMATION

This DFS pertains to the case captioned above:

Case Number and Court in which action was originally filed, if other than direct file into MDL No. 2641: _____

Date this DFS was completed: _____

A. Please provide the following information on the person or persons who provided the information responsive to the questions posed in this DFS:

1. Name;
2. Current position (if no longer employed, last position with Defendant(s));
3. City of employment (if no longer employed, city of residence).

II. CONTACTS WITH TREATING AND EVALUATING PHYSICIANS

Plaintiff has identified each healthcare provider who treated and/or evaluated Plaintiff for deep vein thrombosis, pulmonary embolism, and/or associated conditions that led to the use of Defendants' Bard Inferior Vena Cava Filter, and who prescribed or implanted a Bard IVC Filter, who removed or attempted to remove a Bard IVC Filter. As to each such healthcare provider, provide the following information:

A. CONSULTATION AND OTHER NON-SALES REPRESENTATIVE CONTACTS

As to each identified healthcare provider with whom the Defendants were affiliated, consulted or otherwise had contact outside the context of sales representative contacts, set forth the following:

1. Identify all contacts between the healthcare provider and Bard's Medical Services and Support.

2. Identify all past and present consulting arrangements with the healthcare provider.

3. Identify any document previously produced that references the healthcare provider.

4. Identify and produce all Form 1099's reflecting payments or reimbursements of any nature to the healthcare provider.

5. Identify any Dear Doctor letter or similar communication regarding Bard's IVC filters that concern any safety-related issue and that could have been sent to the healthcare provider (or the hospital or facility where the filter was implanted), and identify any record reflecting actual delivery of the communication to the provider or the facility.

6. Identify (to the extent known) any Bard-sponsored clinical study in which the healthcare provider participated.

7. Identify any training provided to or by the healthcare provider including, but not limited to, date, location, healthcare provider's role, cost for attending such training, and subject matter.

8. Set forth any and all contractual relationships between the healthcare provider(s) and any named Defendant, including, but not limited to:

   a. whether the provider participated in any study or clinical trials as a principal investigator or supervising physician at any study site which was sponsored by Defendant(s) on Defendants' behalf;

   b. whether the provider has spoken on behalf of Defendant(s) or any of its products;

   c. whether the provider has served in any capacity on any advisory board, etc.;

   d. whether the provider has ever served as a Key Opinion Leader or Thought Leader for, or on behalf of, any of the named defendants;

   e. whether the provider has functioned in any capacity promoting Defendants' products;

   f. whether the provider has ever been employed by or under contract to Defendant(s).

9. For each facility where a Bard IVC filter was implanted in the plaintiff, set forth the number and type of Bard Inferior Vena Cava Filter(s) purchased from you, or otherwise provided by you, for a four-year period (spanning from 2 years before the implant until 2 years afterward). If there are no records of filter sales to that facility during the time period in question, identify any distributors known to the Defendants that may have supplied filters to the facility, or the names of all purchasers of filters from the lot number in question

10. Set forth any contact between the Defendants and the healthcare provider with regard to the Plaintiff, this includes, but is not limited to, any information or knowledge Defendants have with respect to research studies conducted on or that include information related to Plaintiffs implant or associated lot number.

B. SALES REPRESENTATIVE AND OTHER RELATED CONTACTS

As to the sales representative assigned to the territory where the implanting facility is located, during the time period when the implant occurred, set forth the following:

1. Identity and last known address and telephone number of the Representative(s).

2. The work history with you and current relationship, if any, between the specified Defendant(s) and the Representative(s).

3. Identity of the Representative(s)' supervisor(s) during his/her Employment.

4. For each Sales Representative, Sales Manager, Marketing Organization Representative, medical liaison, and/or Representative, please produce the most current Curriculum Vitae or Resume. If the Company is not in possession of a Curriculum Vitae or Resume, produce the portion of that person's personnel file that reflects their educational background and experience over the past 10 years.

5. Defendants or their Representatives, Sales Representatives, Representative(s) or Managers have ever provided any of Plaintiffs healthcare provider(s) with Bard Inferior Vena Cava Filter(s) samples, please provide the identity of the person or entity who received the samples, the date(s) the samples were shipped, the date on which the samples were provided, the number and lot numbers of such samples, and the name of the person who provided the samples.

11. Set forth all information provided by the healthcare provider to the Representatives, Sales Representatives, Representative(s) or Managers with regard to the Plaintiff.

12. Set forth all information provided by the Representatives, Sales Representatives, Representative(s) or Managers with regard to the Plaintiffs.

13. State whether the sales representative, Sales Manager, Marketing

Organization Representative, medical liaison, and/or Representative while employed by you, or acting as an agent or independent contractor on your behalf, was ever reprimanded and/or otherwise penalized by any person, entity, or government agency for his/her sales or marketing practices during the period of employment with you, and if so set forth the details thereof.

III. INFORMATION REGARDING THE PLAINTIFF: COMMUNICATIONS AND RELATIONSHIPS WITH PLAINTIFF'S HEALTHCARE PROVIDERS

A. Identify all data, information, objects, and reports in Defendants' possession or control or which have been reviewed or analyzed by Defendants, with regard to the Plaintiffs medical condition; this also includes, but is not limited to, any study or research that includes Plaintiffs specific implant or associated lot number. Attorney-work product is specifically excluded from this request.

B. Identify any direct or indirect contact, either written or oral, between the Plaintiff and any employee or representative of the Defendants, including, but not limited to, pre-operative inquiries, post-operative complaints, "Dear Healthcare Provider" letters, "Dear Doctor" letters, "Dear Colleague" letters or other similar type of document or letter concerning Bard Inferior Vena Cava Filters, recall letters, telephone or email contacts or meetings. This request specifically includes, but is not limited to, calls to the Bard hotline and calls to the Field Assurance Department.

C. Identify and produce any Physician's Information Request Letters ("PIR") or other similar information request that has ever been initiated between the Plaintiff and any employee or representative of the Defendants relating to Bard Inferior Vena Cava Filters, and identify the date of the request and the recipient, the name and address of the sender or requestor, the corresponding bates number of the request, and whether or not a response to the PIR or other similar information request was sent or provided.

D. Produce communications between the Defendants, the sales representative company and/or sales representative(s), Sales Manager, Marketing Organization Representative, medical liaison, and/or Representative identified in section B above and Plaintiff, to the extent not contained in the complaint file, if any, and identify the Bates numbers of such communications.

E. Identify all Adverse Event Reports, Medical Devise Reports, and all versions of any MedWatch forms and/or any other documents submitted to the FDA or any other government agency with regard to the Plaintiff.

F. If you have any evidence or records indicating or demonstrating the possibility that any person, entity, condition, or product, other than the Defendants and their product(s), is a cause of the Plaintiffs injuries, ("Alternate Cause") set forth:

1. Identify the Alternate Cause with specificity.

2. Set forth the date and mechanism of alternate causation,

G. In Plaintiffs Fact Sheet, Plaintiff identified his/her Implanting Healthcare Provider(s). For each listed provider, please state and produce the following: Do you have or have you had access to any database or information which purports to track any of Plaintiffs Implanting Healthcare Provider's implanting practices with respect to Bard Inferior Vena Cava Filter(s). If yes, please produce or identify the database or document which captures that information.

IV. MANUFACTURING INFORMATION

A. Identify the lot number(s) for the device(s) implanted into the Plaintiff.

B. Identify the location and date of manufacture for each lot set forth in response to A and B above.

C. Identify the date of shipping and sale, and the person or entity purchasing, each of Plaintiffs device(s).

E. Identify all manufacturing facilities and associated lot number(s) of Plaintiffs implanted device(s).

F. Other than Bard related entities, and those entities listed in Sections IV(A-F) herein, the chain of custody of the device from Bard to the healthcare provider.

V. PLAINTIFF'S MEDICAL CONDITION:

A. Have you been contacted by Plaintiff, any of his/her physicians, or anyone on behalf of Plaintiff concerning Plaintiff? If yes, please provide, to extent permitted by CMO 7 the following:: a) the name of the person(s) who contacted you; b) the person(s) who were contacted including their name, address and telephone number; and c) produce or identify any and all documents which reflect any communication between any person and you concerning Plaintiff.

VI. DOCUMENTS

Please ensure that the production of documentation includes specific reference to the question to which the documentation is provided in response. Documentation is defined to include all forms of documents, including, but not limited to, paper, email, video, audio, spreadsheets, or otherwise.

A. Identify and attach complete documentation of all information set forth in I through IV above; except, you may identify but not serve copies of medical records that were provided to Defendants by Plaintiffs' counsel.

B. Aside from any privileged materials, identify and attach all records, documents, and information that refer or relate to the Plaintiff in Defendants' possession or control, to the extent not identified and attached in response to a prior question.

C. Produce a true and complete copy of the Device History Record for the Plaintiffs lot number(s).

D. Produce a true and complete copy of the complaint file relating to the Plaintiff.

_____

[Bard Defendant Name]

_____

[Title]

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,

No. MDL 15-02641-DGC

SECOND AMENDED CASE MANAGEMENT ORDER NO. 4

(Master Complaint, Master Responsive Pleading, Use of Short Form Complaint, Waiver of Service for Bard Defendants, and Answer and General Denial in Cases Subsequently Transferred to MDL 2641)

The parties previously submitted a Master Long Form Complaint and Jury Demand (previously docketed as Doc. 303-1) and a Master Responsive Pleading (previously docketed as Doc. 303-3). The Court has reviewed these proposed pleadings, finds them sufficient, and directs the Clerk to file them as separate documents in the Court's docket.[1] The parties have also submitted a proposed Second Amended Short Form Complaint, a copy of which is attached to this order. The Court also finds this proposed pleading to be sufficient.

IT IS ORDERED:

All allegations pled in the Master Complaint and all responses pled in the Master Responsive Pleading are deemed pled in any previously filed Complaint and Responsive Pleading in this MDL proceeding, except as expressly noted below. They are also deemed pled in any Short Form Complaint (attached to CMO No. 4, Doc. 363) or Second

[1] The reference to "Federal Rule of Evidence 8" on the first page of the Master Complaint shall be deemed to be a reference to Federal Rule of Civil Procedure 8.

Amended Short Form Complaint (attached to this Order) and Entry of Appearance filed after the entry of this order, except that the Master Complaint applies only against the Defendant or Defendants identified in such future-filed Short Form or Second Amended Short Form Complaints.

The following cases will not be governed by the Master Complaint and Master Responsive Pleading, but will continue to be governed by the complaints (including any amended complaints) and answers filed in the various transferor courts prior to transfer:

Plaintiff	Original Jurisdiction
1. Cason, Pamela	GA – N.D. Ga. 1:12-cv-1288
2. Coker, Jennifer	GA – N.D. Ga. 1:13-cv-515
3. Ebert, Melissa	PA – E.D. Pa. 5:12-cv-1253
4. Fox, Susan	TX – N.D. Tex. 3:14-cv-133
5. Henley, Angela	WI – E.D. Wis. 2:14-cv-59
6. Keen, Harry	PA – E.D. Pa. 5:13-cv-5361
7. Ocasio, Denise	FL – M.D. Fla. 8:13-cv-1962
8. Rivera (McClarty), Vicki	MI – E.D. Mich. 4:14-cv-13627
9. Smith, Erin	TX – E.D. Tex. 1:13-cv-633
10. Tillman, Lessie	FL – M.D. Fla. 3:13-cv-222

On or after **December 28, 2015,** any plaintiff whose case would be subject to

transfer to MDL 2641 may file his or her case directly in this Court by using the Short Form Complaint (Doc. 363). After **April 20, 2016,** Plaintiffs may use the use the Second Amended Short Form Complaint attached to this Order. If such a case is filed in this Court without the use of the Second Amended Short Form Complaint, Plaintiffs' Co-Lead Counsel shall promptly advise the filing party to file an amended complaint using the Second Amended Short Form Complaint. If the filing party fails to do so, Plaintiffs' Co-Lead Counsel shall promptly notify the Court.

Defendants are not required to file answers to Short Form, Amended Short Form, or Second Amended Short Form Complaints. An Entry of Appearance shall constitute a denial of all allegations in the Short Form, Amended Short Form, or Second Amended Short Form Complaints except as herein provided, and an assertion of all defenses included in the Master Responsive Pleading. By filing an Entry of Appearance in response to a Short Form, Amended Short Form, or Second Amended Short Form Complaints, in lieu of an answer, Defendants do not waive any defenses, including jurisdictional and service defenses.

Civil actions in this MDL were transferred to this Court by the Judicial Panel on Multidistrict Litigation for coordinated or consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. Upon completion of the pretrial proceedings related to a civil action as determined by this Court, the case shall be transferred pursuant to 28 U.S.C. § 1404(a) or § 1406(a) to the District Court identified in the Short Form, Amended Short Form, or Second Amended Short Form Complaints, provided the parties choose not to waive *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). The fact that a case was filed directly in this District and MDL proceeding shall not constitute a determination by this Court that jurisdiction or venue are proper in this District, and shall not result in this Court being deemed the "transferor court" for purposes of this MDL. In addition, filing a Short Form, Amended Short Form, or Second Amended Short Form Complaint in this District shall have no impact on the conflict of law rules to be applied to

the case. Instead, the law of the jurisdiction where the case is ultimately transferred will govern any conflict of law. Prior to transfer, Defendants may object to the district specified in the Short Form, Amended Short Form, or Second Amended Short Form Complaint, based on venue or jurisdiction (including a lack of personal jurisdiction based on *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014)), and propose an alternative jurisdiction for the Court's consideration.

Subject to the conditions set forth in this order, Defendant C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") waive service of process in cases filed in this Court using the Short Form, Amended Short Form, or Second Amended Short Form Complaint and in which they are named as defendants and one or more IVC filter products either manufactured or distributed by Bard is alleged to be at issue. For such cases, Plaintiffs shall send a Short Form, Amended Short Form, or Second Amended Short Form Complaint and a request for waiver of service pursuant to the provisions of Fed. R. Civ. P. 4 to Richard B. North, Jr. by email to richard.north@nelsonmullins.com; maria.turner@nelsonmullins.com; and matthew.lerner@nelsonmullins.com. Counsel for Bard shall return the signed waiver requests to the Court within the time permitted by Fed. R. Civ. P. 4. Plaintiffs submitting a request for waiver shall not seek to hold Bard in default for failure to timely answer or otherwise respond to a complaint in which service has been accomplished pursuant to the terms of this order without first giving Bard written notice of the alleged default and ten business days in which to cure any alleged default.

Prior to a Plaintiff's attorney filing a Short Form, Amended Short Form, or Second Amended Short Form Complaint in this Court, that attorney must register for or already have a District of Arizona CM/ECF log-in name and password. If the Plaintiff's attorney does not already have a District of Arizona CM/ECF log-in name and password, that attorney **must** file the Short Form, Amended Short Form, or Second Amended Short Form Complaint in paper form with the Clerk of Court and simultaneously file an Application of Attorney for Admission to Practice Pro Hac Vice pursuant to LRCiv 83.1(b)(2)

(including all necessary attachments and filing fee).

Additionally, with respect to cases which are originally filed in courts other than this Court which are then subsequently transferred to MDL 2641 pursuant to 28 U.S.C. § 1407, Defendants' may file an Answer and General Denial with Respect to Cases Subsequently Transferred to MDL 2641, incorporating the defenses and denials set forth in the Master Answer and generally denying the plaintiffs' allegations. This short-form answer shall serve as the responsive pleading. Defendants shall have 60 days from the date any such case is opened in this Court to file any motion for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6) and 12(h)(2), and the plaintiff(s) shall have 30 days to respond.

Dated this 20th day of April, 2016.

David G. Campbell
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. 2:15-MD-02641-DGC **SECOND AMENDED MASTER SHORT FORM COMPLAINT FOR DAMAGES FOR INDIVIDUAL CLAIMS AND DEMAND FOR JURY TRIAL**

Plaintiff(s) named below, for their Complaint against Defendants named below, incorporate the Master Complaint for Damages in MDL 2641 by reference (Doc. 364). Plaintiff(s) further show the Court as follows:

1. Plaintiff/Deceased Party:

_____

2. Spousal Plaintiff/Deceased Party's spouse or other party making loss of consortium claim:

_____

3. Other Plaintiff and capacity (i.e., administrator, executor, guardian, conservator):

_____

4. Plaintiff's/Deceased Party's state(s) [if more than one Plaintiff] of residence at the time of implant:

_____

5. Plaintiff's/Deceased Party's state(s) [if more than one Plaintiff] of residence at the time of injury:

_____

6. Plaintiff's current state(s) [if more than one Plaintiff] of residence:

_____

7. District Court and Division in which venue would be proper absent direct filing:

_____

8. Defendants (check Defendants against whom Complaint is made):

□ C. R. Bard Inc.

□ Bard Peripheral Vascular, Inc.

9. Basis of Jurisdiction:

□ Diversity of Citizenship

□ Other: _____

a. Other allegations of jurisdiction and venue not expressed in Master Complaint:

_____

_____

_____

10. Defendants' Inferior Vena Cava Filter(s) about which Plaintiff(s) is making a claim (Check applicable Inferior Vena Cava Filter(s)):

□ Recovery® Vena Cava Filter

□ G2® Vena Cava Filter

□ G2® Express Vena Cava Filter

□ G2® X Vena Cava Filter

□ Eclipse® Vena Cava Filter

□ Meridian® Vena Cava Filter

□ Denali® Vena Cava Filter

□ Other: _____

11. Date of Implantation as to each product:

_____

_____

12. Counts in the Master Complaint brought by Plaintiff(s):

□ Count I: Strict Products Liability – Manufacturing Defect

□ Count II: Strict Products Liability – Information Defect (Failure to Warn)

□ Count III: Strict Products Liability – Design Defect

□ Count IV: Negligence - Design

□ Count V: Negligence - Manufacture

□ Count VI: Negligence – Failure to Recall/Retrofit

□ Count VII: Negligence – Failure to Warn

□ Count VIII: Negligent Misrepresentation

□ Count IX: Negligence *Per Se*

□ Count X: Breach of Express Warranty

□ Count XI: Breach of Implied Warranty

□ Count XII: Fraudulent Misrepresentation

□ Count XIII: Fraudulent Concealment

□ Count XIV: Violations of Applicable _____ (insert state) Law Prohibiting Consumer Fraud and Unfair and Deceptive Trade Practices

□ Count XV: Loss of Consortium

□ Count XVI: Wrongful Death

□ Count XVII: Survival

□ Punitive Damages

□ Other(s): _____ (please state the facts supporting this Count in the space immediately below)

_____

_____

_____

_____

_____

_____

13. Jury Trial demanded for all issues so triable?

□ Yes

□ No

RESPECTFULLY SUBMITTED this ____ day of _____, 20___.

[SIGNATURE BLOCK]

By: */s/* _____
[Attorney name/address]

I hereby certify that on this ____ day of _____, 20___, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ _____